(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
2 October 2003 (02.10.2003)

PCT

(10) International Publication Number
WO 03/080155 A1

(51) International Patent Classification[7]: A61M 5/00

(21) International Application Number: PCT/US03/07068

(22) International Filing Date: 7 March 2003 (07.03.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/094,406 8 March 2002 (08.03.2002) US

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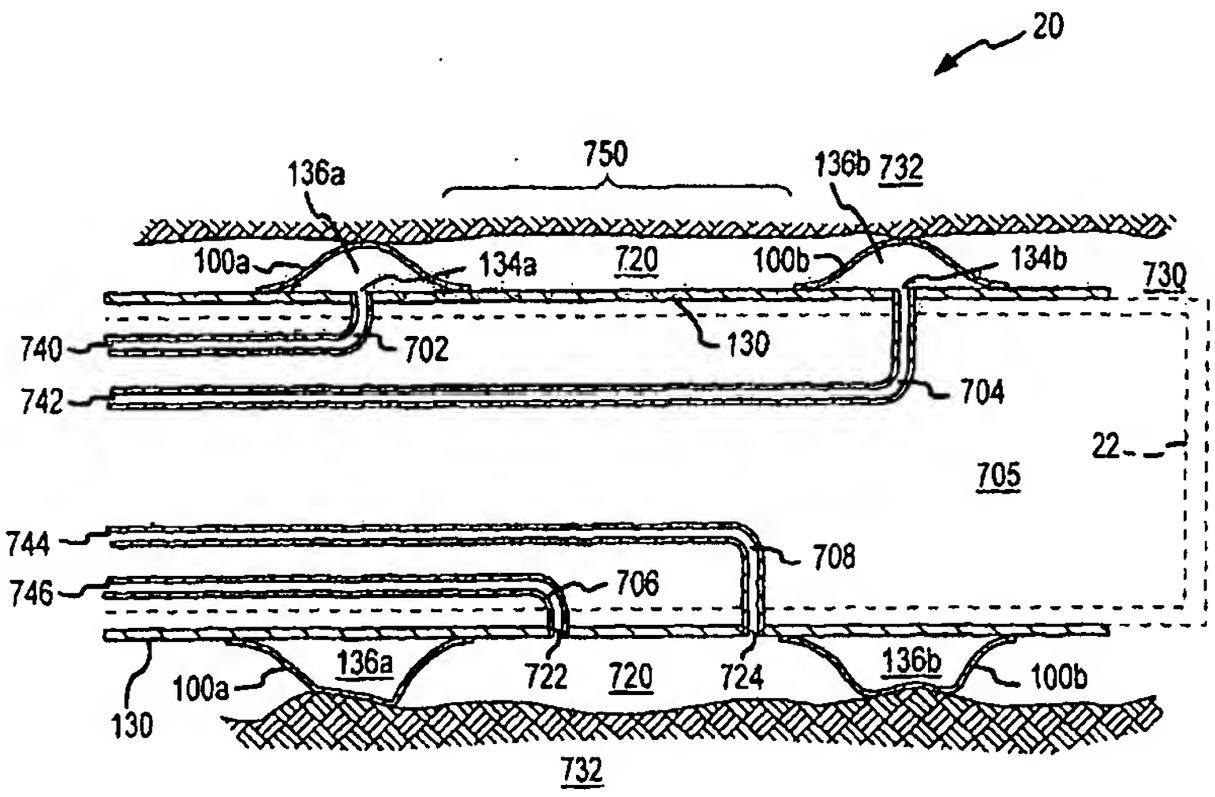
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: INFLATABLE MEMBER FOR AN ENDOSCOPE SHEATH



(57) Abstract: Apparatus and methods for attaching and forming enclosed inflatable members on an endoscope assembly (10) with a disposable sheath (103) are disclosed. In one embodiment, an apparatus includes a flexible and resilient cuff member (100) that is positioned on the outer surface of the disposable sheath and sealably and fixedly bonded to the sheath cover material (130) at the cuff edges to form an annular space (136) capable of being inflated. The inflatable member (100) formed thereby is inflated through a lumen (122) internal to the sheath that has an opening (134) into the interior annular space. The inflatable member may be inflated to exert a longitudinal force on the insertion tube (101), thereby moving the endoscope assembly along a body passage. Alternately, a sheath may include a plurality of inflatable cuffs that may be inflated to create an isolated space therebetween within the body passage.

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INFLATABLE MEMBER FOR AN ENDOSCOPE SHEATH

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of pending United States Patent Application No. 09/702,155, filed October 30, 2000.

TECHNICAL FIELD

This invention relates generally to endoscopy, and more particularly to inflatable members attached to an endoscopic instrument.

BACKGROUND OF THE INVENTION

The use of endoscopes for diagnostic and therapeutic purposes is widespread. For example, there are upper endoscopes for examination of the esophagus, stomach and duodenum, colonoscopes for the examination of the colon, angioscopes for vascular examination, bronchoscopes for examining the bronchi, laparoscopes for examining the peritoneal cavity, and arthroscopes for the examination of joint spaces. The following discussion applies to all of these types of endoscopes.

An endoscope for examining the bronchial tract and conducting transbronchial biopsies is a good example of the usefulness of endoscopic technology. These devices, known as flexible bronchoscopes, are widely used in diagnosing pulmonary diseases since they are capable of reaching the more distal bronchi in the bronchial tract. To properly navigate and view a bronchial area, the bronchoscope is generally structured to contain a fiber optic bundle within the elongated probe section. Alternatively, the bronchoscope may utilize other means to view the bronchial area, such as a video device positioned within the bronchoscope. In addition to providing a direct viewing capability, flexible bronchoscopes generally possess a means to remove tissue samples, or other material from the bronchial tract

for biopsy or culture purposes. Tissue samples for biopsy purposes may be collected using a biopsy forceps extending from the distal end of the bronchoscope or by brushing the suspect area to capture cellular material for subsequent microscopic examination. Another commonly used technique to collect cellular material is to wash, or lavage, the suspect area. When a lavage procedure is used, a solution is injected into the bronchial passage and subsequently withdrawn by suction through the distal end of the broncoscope to capture cellular material. Following withdrawal of the lavage fluid, the cellular material may be subjected to a cytological examination or culture.

One difficulty encountered in the use of endoscopes is continuously maintaining the endoscopic probe in a selected location within a body passage during the examination. Movement of the endoscopic probe while it is positioned within a body passage may occur for a number of reasons. For example, movement of the endoscope may occur due to an unintended bodily movement of the operator while the patient is undergoing the examination, or by an involuntary movement of the patient in response to the examination. Once the distal end of the endoscope has been dislodged from its intended location, it must be carefully repositioned before the examination may be resumed. Movement of the endoscope within a body passage is particularly pronounced during bronchoscopic examinations, since the patient must continue to breathe during the examination. Further, involuntary bronchospasmodic events within the bronchial passages may occur during the examination that will disrupt the location of the distal end of the bronchoscope. A significant additional difficulty resulting from unintended patient movement may arise when a biopsy procedure is conducted. Since a biopsy forceps or brush is generally used, an uncontrolled or unintended cutting of tissue in the passage due to patient movement may lead to hemoptysis. Moreover, since the biopsy forceps, or brush may reach and perforate the pleura, pneumothorax may also occur.

Still another difficulty encountered in the use of endoscopes for diagnostic purposes is the inability to sealably isolate a portion of the endoscope from the remainder of the body passage during an endoscopic examination. To facilitate internal viewing of a passage, for example, the fluid occupying the cavity is generally removed by means of a suction channel in the endoscope, which may be followed by the introduction of a gas through an additional channel in the endoscope to distend the internal space. Other endoscopic applications may require that a fluid be retained within the portion of the body passage that has been sealably isolated. For example, in transbronchial diagnostic procedures such as bronchoalveolar lavage, the bronchoscope is used to gently irrigate the air spaces in a distal air passage with a solution. Isolation of the solution to the region surrounding the distal end of the bronchoscope is required so that cellular samples removed during the lavage are sufficiently localized to be of diagnostic value. In particular, when collecting samples by lavage for use in the diagnosis of infectious pulmonary diseases, the sample must not be contaminated by bacterial or other agents transported to the distal end of the probe by the unrestrained movement of the solution through the passage.

Yet another difficulty encountered in the use of endoscopes occurs when the endoscope must be positioned at a relatively deep location within a body passage, so that a relatively long portion of the endoscope must be inserted into the patient. In such cases, the endoscope may be resistant to small, or incremental movements within the passage. Moreover, in certain cases, the endoscope length may develop sufficient resistance to further inward movement, so that the endoscope is prevented from extending to the intended location. Similar difficulties may also occur when the passage is relatively short, but includes relatively highly curved segments. Since the operator is generally limited to positional manipulations of exposed portions of the endoscope, considerable difficulty may be encountered in properly positioning the endoscope within body passages under these conditions.

Increasingly, endoscopes are used with disposable sheaths that are positioned over the insertion tube of the endoscope to avoid the communication of disease from one patient to another. An additional advantage of the disposable sheath is that it allows the device to be used at more frequent intervals, since the need for lengthy cleaning and sterilization procedures is largely eliminated. Generally, the sheath is comprised of a flexible, thin, resilient material, such as latex, or other similar materials, that fits over and surrounds the insertion tube of the endoscope so the insertion tube is completely isolated from contaminants. The sheath is generally further comprised of a viewing window at the distal end, and may include a plurality of internal channels, or lumens, through which biopsy samples or fluids may be either introduced or removed. Accordingly, an additional difficulty encountered in the use of endoscopes concerns the incorporation of positioning and passage-blocking means into the disposable outer sheath.

Consequently, there exists a need in the art for an apparatus that will continuously maintain an endoscopic probe in a selected position within a body passage during the examination. In addition, the apparatus must be able to sealably close the passage to either retain fluids within a closed space, or to prevent a fluid from reoccupying the space during an examination. Further, there exists a need in the art for an apparatus that permits an endoscopic probe to be properly positioned within a long body passage, and/or where the passage is highly curved. Finally, the apparatus must be compatible with disposable sheaths used with endoscopes.

SUMMARY OF THE INVENTION

The invention is directed towards apparatus and methods for attaching and forming enclosed inflatable members on an endoscope assembly with a disposable sheath. In one aspect, an apparatus in accordance with the invention includes a flexible and resilient cuff member that is positioned on the outer surface of the disposable sheath and sealably and

fixedly bonded to the sheath cover material at the cuff edges to form an annular space capable of inflation. The inflatable member formed thereby is inflated through a lumen internal to the sheath that has an opening into the interior annular space. In another aspect, the annular space may be divided into separate inflatable lobes. In still another aspect, the cuff member is a flexible and resilient enclosed member that is substantially toroidal in shape that is positioned on the outer surface of the sheath. In a further aspect, the inflatable member is formed from an excess length of sheath cover material disposed on the disposable sheath. A single reentrant fold of sheath material is formed with an edge that is sealably and fixedly bonded to the sheath cover material to form an annular space capable of inflation. In still another aspect, the excess length of cover material may be used to form members with dual reentrant folds that comprise inflatable members with single and dual inflatable lobes. In another aspect, at least a pair of enclosed inflatable members are spaced apart along the sheath of an endoscope insertion tube, which has a plurality of openings that project through the sheath to communicate a fluid to the space formed between the inflatable members. In still another aspect, at least a single enclosed inflatable member that has a first portion capable of a first expansion when inflated, and a second portion capable of a second expansion when inflated, is positioned on an endoscope sheath of an insertion tube to assist in the movement of the endoscope along a body passage.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a partial cross-sectional view of an endoscope assembly with an inflatable cuff according to an embodiment of the invention.

Figure 2 is a cross-sectional view of an inflatable cuff according to another embodiment of the invention.

Figure 3 is a cross-sectional view of an inflatable cuff according to still another embodiment of the invention.

Figure 4 is a cross-sectional view of an inflatable cuff according to yet another embodiment of the invention.

Figure 5 is a cross-sectional view of an inflatable cuff according to another alternative embodiment of the invention.

Figure 6 is a cross-sectional view of an inflatable cuff according to still another alternative embodiment of the invention.

Figure 7 is a cross-sectional view of an endoscope assembly with inflatable cuffs according to another embodiment of the invention.

Figure 8 is a cross-sectional view of an endoscope assembly with inflatable cuffs according to still another embodiment of the invention.

Figure 9 is a cross-sectional view of an endoscope assembly with inflatable cuffs according to still another embodiment of the invention.

Figure 10 is a cross-sectional view of an endoscope assembly with inflatable cuffs according to still another embodiment of the invention.

Figure 11 is an isometric view of an endoscope assembly with inflatable cuffs according to yet another embodiment of the invention.

Figure 12 is a partial side view of an endoscope assembly with inflatable cuffs according to still yet another embodiment of the invention.

Figure 13 is a partial side view of an endoscope assembly with inflatable cuffs according to still yet another embodiment of the invention.

Figure 14 is a partial side view of an endoscope assembly with inflatable cuffs according to still yet another embodiment of the invention.

Figure 15 is an end elevational view of the endoscope assembly of Figure 1 with the inflatable cuff in the inflated position.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is generally directed to inflatable members attached to an endoscope. Many of the specific details of certain embodiments of the invention are set forth in the following description and in Figures 1 through 15 to provide a thorough understanding of such embodiments. One skilled in the art will understand, however, that the present invention may have additional embodiments, or that the present invention may be practiced without several of the details described in the following description.

In the drawings, like reference numbers identify similar elements or steps. Further, it is understood that the inflatable members depicted in Figures 1 through 14 may assume a variety of sizes and shapes that depend on the amount of internal pressurization and/or the internal shape of a body cavity. Accordingly, for clarity of illustration, and to properly illustrate internal features of the various embodiments illustrated in Figures 1 through 14, the embodiments are shown at a generally intermediate stage of inflation.

Figure 1 is a partial cross sectional view of an endoscope assembly 10 that includes a sheath 103 having an inflatable cuff 100 in accordance with an embodiment of the invention. In this embodiment, the inflatable cuff 100 is circumferentially disposed about a body portion of the sheath 103, the body portion being sized to at least partially encapsulate an insertion tube 101 of an endoscope of the type shown, for example, in Figure 11.

When inflated, the cuff 100 may be symmetrically or asymmetrically disposed about the insertion tube 101. For example, Figure 15 is an end elevational view of the endoscope assembly 10 with the inflatable cuff 100 shown in an inflated position 105. As shown in Figure 15, in this embodiment, the inflatable cuff 100 is symmetrically circumferentially disposed about the insertion tube 101. In alternate embodiments, the inflatable cuff 100 may assume any desired shape, including, for example, an eccentrically-disposed circular shape 107 (Figure 15) that is not symmetrically disposed about the insertion tube 101, or a non-circular, asymmetric shape 109 (Figure 15), or any other suitable shape.

The insertion tube 101 can have a variety of cross section shapes, such as circular, semicircular, etc., and is fabricated from a resilient material so that an insertion tube wall 102 may be flexed. The insertion tube 101 also has an internal space 104 that is structured to permit the illumination of tissue in internal passages, and to convey an image of the illuminated area from the distal end 110 of the endoscope to an external viewing device (not shown).

With reference still to Figure 1, the endoscope sheath 103 has a transparent viewing window 118 located at the distal end 110 of the disposable sheath 103 to allow the image to be conveyed to the external viewing device. The window 118 may also be comprised of a lens capable of focusing an image on an image sensing device. The sheath 103 also has a plurality of internal lumens to accomplish specific tasks. For example, a lumen 124 may be provided to direct a flow of rinse water over the viewing window 118 in order to rinse vision-impairing matter from the window 118. A lumen 122 that is open at the distal end 110 may be used to capture a biopsy sample taken from the surrounding tissue area by means of an elongated forceps, or brush (not shown). Alternatively, the lumen 122 may be used to transfer a solution into a body passage during a lavage procedure. Further, the lumen 122 may also be used to transfer a compressed gas into a body passage in order to distend the passage for better optical viewing or biopsy sampling. An additional lumen 120 that is in fluid communication with a pressurized fluid source (not shown) is used to inflate an inflatable endoscope cuff 100, which will be described in greater detail below. The internal lumens 120, 122 and 124 are comprised of a resilient material to maintain flexibility of the sheath 103. The sheath 103 is covered with a flexible, resilient cover material 130 such as latex, polyvinylchloride, or polyurethane. Alternatively, other equally suitable materials for the cover material 130 are KRATON®, available from the GLS Corporation of McHenry, IL, and C-FLEX®, available from Consolidated Polymer Technologies, Inc. of Largo, FL.

Still referring to Figure 1, the inflatable endoscope cuff 100 is comprised of a circular member positioned on the outer surface of the sheath 103. Although only a single inflatable cuff 100 is shown for clarity of illustration, it is understood that a plurality of cuffs 100 may be positioned along the length of the endoscope assembly 10, and that the plurality of cuffs 100 may be positioned at varying relative distances. The inflatable cuff 100 may be located at any location along the working length of the endoscope assembly 10, and forms a closed annular space 136 that is capable of inflation by a pressurized fluid. An opening 134 projects through the cover material 130 and through the wall of the lumen 120 to permit the pressurized fluid retained within the lumen 120 to enter the inflatable cuff 100. To retain the cuff 100 on the surface of the sheath 103, and to retain the pressurized fluid within the annular space 136, the cuff 100 is sealably fastened to the surface of the sheath 103 at the cuff edges 138 with a suitable adhesive placed between the cuff edge 138 and the cover material 130. An example of a suitable adhesive is cyanoacrylate, although other equivalent adhesives exist. Alternatively, the cuff edges 138 may be joined to the cover material 130 either by thermally fusing the cuff edges 138 to the cover material 130, or by wrapping lengths of a retaining cord 131, such as a surgical-type thread or other suitable material, over the cuff edge 138 and securely tying the ends to sealably fasten the cuff edges 138 to the cover material 130, although other methods for attaching the cuff edges 138 to the cover material 130 may also be used.

The inflatable cuff 100 may be formed from latex, KRATON®, or C-FLEX®, although other suitable flexible and resilient materials may be used. For example, soft polyurethane may also be used. Preferably, the inflatable cuff 100 is formed from a flexible and resilient material with a thickness that ranges between 0.003 and 0.010 inches, with a durometer value of between approximately 30 and approximately 50. Alternatively, the cuff 100 may also be formed from a relatively inelastic material, so that it exhibits a relatively baggy shape when not inflated.

With reference now to Figure 2, a partial cross sectional view of the endoscope assembly 10 with an alternative embodiment of an inflatable endoscope cuff 200 is shown. As shown therein, the inflatable endoscope cuff 200 is comprised of a resilient toroidally-shaped member 202 with an internal radius r and an external radius R. An opening 134 projects through the cover material 130 and through the wall of the lumen 140 to permit a pressurized fluid retained within the lumen interior space 112 to enter the inflatable member 202 through an opening 210 in the interior diameter of the member 202. To sealably retain the pressurized fluid within the annular space 136, the toroidally-shaped member 202 is sealably fastened to the surface of the sheath 103 at a location that is closely proximate to the opening 134. Moreover, to positionally retain the member 202 in the desired location on the surface of the sheath 103, it is preferable to join the interior diameter of the member 202 to the cover material 130 along a circumferential contact area 220 to ensure that the member 202 maintains its position on the endoscope assembly 10.

Figure 3 shows a partial cross sectional view of the endoscope assembly 10 with still another alternative embodiment of an inflatable endoscope cuff 300. As shown in Figure 3, the inflatable endoscope cuff 300 is comprised of a resilient circular member 302 positioned on the outer surface of the sheath 103. In this embodiment, the length of the endoscope cuff 300 is sufficient to allow the formation of a pair of inflatable annular lobes 310 and 320 by attaching the circular member 302 to the cover material 130 at an approximate midpoint location 350 of the cuff 300. The development of an inflatable endoscope member with dual lobes is regarded as particularly advantageous since the dual lobes are regarded as more effective in conforming to irregular internal surfaces in body passages.

Still referring to Figure 3, the cuff 300 may be retained at the midpoint location 350, and may be adhesively or thermally bonded to the cover material 130. Alternatively, the cuff may be attached to the cover material 130 at the mid point location 350 by a length of

thread 131 (as shown in Figure 1) wrapped around the cuff 300 that is securely knotted, although other methods may also be used. To retain the pressurized fluid within the inflatable annular lobes 310 and 320, cuff edges 340 are sealably joined to the cover material 130 using an adhesive or thermal bonding method as previously described. Openings 134a and 134b project through the cover material 130 and through the lumen wall 140 to permit the pressurized fluid retained in the lumen interior space 112 to enter the lobes 310 and 320 during inflation.

Turning now to Figure 4, a partial cross sectional view of the endoscope assembly 10 with yet another alternative embodiment of an inflatable endoscope member 400 is shown. The endoscope assembly 10 according to this embodiment advantageously allows an inflatable member to be formed on the disposable sheath 103 without placing a separate circumferential member on the disposable sheath 103. The inflatable member 400 is formed by providing an excess length of the cover material 130 on the sheath 103 that may be drawn along the surface of the sheath 103 by an edge fold 440 that extends circumferentially around the sheath 103 to form a reentrant fold 450 in the cover material 130 that also extends circumferentially around the disposable sheath 103. The edge fold 440 is subsequently sealably attached to the cover material 130 at a surface location 460 to form a closed annular space 410 that is capable of being inflated. The sealable attachment between the edge fold 440 and the cover material 130 may be comprised of an adhesive or thermal bond. Alternatively, the attachment may be comprised of a length of retaining cord 131 (*e.g.* surgical-type thread, as shown in Figure 1) that is wrapped over the edge fold 440 and securely knotted, although other methods may also be used. An opening 420 projects through the cover material 130 and is aligned with the opening 134 through the wall of the lumen 140 to permit the pressurized fluid retained within the lumen interior space 112 to enter the inflatable annular member 400 during inflation. The member 400 may be sealably fastened to the surface of the sheath 103 at a location 412 that is closely proximate to the opening 134 to

ensure that the lumen opening 134 in the lumen wall 140 remains in substantial alignment with the opening 420 through the cover material 130.

Figure 5 shows a partial cross sectional view of the endoscope assembly 10 with still another alternative embodiment of an inflatable endoscope member 500. As in the previous embodiment, the inflatable endoscope member 500 is advantageously formed from an excess length of the cover material 130 that is disposed on the sheath 103. As shown in Figure 5, the excess length of the cover material 130 is drawn in a first direction along the surface of the sheath 103 to form a first reentrant fold 530 with a first edge fold 570. The first edge fold 570 is positioned approximately adjacent to the lumen opening 134. A second reentrant fold 540 is then formed in the cover material 130 by drawing the excess length in a second direction that is opposite to the first, to form a second edge fold 580 that is also positioned approximately adjacent to the lumen opening 134. When positioned approximately adjacent to the opening, the first edge fold 570 and the second edge fold 580 form an opening 590 into the inflatable enclosed annular space 510. The first and second reentrant folds 530 and 540 are sealably attached to the lumen wall 140 at locations 550 and 560, respectively, to ensure that the lumen opening 134 remains in substantial alignment with the opening 590. Adhesive or thermal bonding may form the sealable attachment at locations 550 and 560. As an alternative, a retaining cord 131 (*e.g.* surgical-type thread, as shown in Figure 1) may be inserted into the first reentrant fold 530 through the opening 520 and also inserted into the second reentrant fold 540 through the opening 525, both lengths of retaining cord being wrapped around the circumference of the disposable sheath 103 and securely knotted to retain the inflatable member 500 in position on the sheath 103, although other methods may also be used.

Turning now to Figure 6, a partial cross sectional view of the endoscope assembly 10 with still another alternative embodiment of an inflatable endoscope member 600 is shown. The inflatable endoscope member 600 is similarly advantageously formed from an

excess length of the cover material 130 that is disposed on the sheath 103. Drawing the excess length of cover material 130 along the surface of the sheath 103 in a first direction to form a first reentrant fold 660 with a first edge fold 670 forms the inflatable member 600. The first edge fold 670 is then positioned approximately adjacent to the opening 134a. Drawing the excess length in a second direction that is opposite to the first direction then forms a second reentrant fold 665 with a second edge fold 675. The second edge fold 675 is similarly positioned approximately adjacent to the opening 134b. The inflatable member 600 is divided into a pair of inflatable lobes 610 and 620 by attaching the cover material comprising the member 600 to the lumen wall 140 at an approximate midpoint location 680. The inflatable lobes 610 and 620 are inflated when pressurized fluid retained within the lumen interior space 112 enters the lobes through openings 134a and 134b. The first and second reentrant folds 660 and 665 are sealably attached to the lumen wall 140 at locations 672 and 674 to ensure that the lumen openings 134a and 134b remain in substantial alignment with the lobe entrances 661 and 662. As previously described, adhesive or thermal bonding may be used to form the sealable attachment at locations 672, 674 and 680. As an alternative, a retaining cord 131 may be used to retain the position of the inflatable member on the sheath 103, although other methods may also be used.

Figure 7 is a cross-sectional view of an endoscope assembly 20 in accordance with yet another alternative embodiment of the invention. The assembly 20 is comprised of a pair of flexible, resilient inflatable cuffs 100a and 100b that are positioned on an outer surface of a disposable sheath 130. The cuffs 100a and 100b are spaced apart along the length of the endoscope assembly 20 to define an inter-cuff length 750. The sheath 130 encloses an interior space 705, and may be positioned on an insertion tube 22 of an endoscope 21 of the type shown, for example, in Figure 11.

Referring now to Figure 11, an endoscope assembly 1000 according to an embodiment of the invention is shown. The endoscope assembly 1000 includes an endoscope

21 having an elongated insertion tube 22 that is comprised of a resilient material so that the tube may be flexed as it is positioned within an internal body passage 730. The insertion tube 22 may be rigid, partially flexible or entirely flexible. The insertion tube 22 includes a distal portion 1002 that may be inserted into a body cavity of a patient (not shown) and a working end 1004. The endoscope 21 includes a headpiece 1006 that remains external to the patient during an endoscopic procedure. In the embodiment shown in Figure 11, the headpiece 1006 includes an eyepiece 1008 for viewing the scene through a viewing lens 1011 at the working end 1004 of the insertion tube 22, a pair of bending control knobs 1012 for manipulating the position of the distal portion 1002 of the insertion tube 22, and a pair of fluid control actuators 1014 for controlling the flow of fluids through tubes 1016 to (or from) the working end 1002. Endoscopes 21 of the type generally shown in Figure 11 are described more fully, for example, in U.S. Patent No. 5,931,833 to Silverstein, U.S. Patent No. 5,483,951 to Frassica and Ailinger, and U.S. Patent No. 4,714,075 to Krauter and Vivenzio, which patents are incorporated herein by reference.

Referring now to Figures 7 and 11, the sheath 130 shows a pair of inflatable cuffs 100a and 100b. It is understood, however, that the sheath 130 may include a plurality of inflatable cuffs located along the length of the sheath 130, and that the inflatable cuffs may be positioned along the length of the sheath 130 at varying inter-cuff lengths 750. Further, the inflatable cuffs positioned along the length of the sheath 130 may be comprised of any of the inflatable cuffs previously shown in Figures 2 through 6. Moreover, any combination of the inflatable cuffs previously shown in Figures 2 through 6 may be positioned along the length of the sheath 130.

Referring again to Figure 7, inflation lumens 702 and 704 are positioned within the interior space 705 of the endoscope 20. The inflation lumens 702 and 704 are fluidly connected to a source of an inflation fluid (not shown) at lumen ends 740 and 742. The lumens 702 and 704 fluidly communicate through openings 134a and 134b to allow the

inflation fluid to be separately and selectively introduced into the annular spaces 136a and 136b. In alternate embodiments, the pair of lumens 702 and 704 may be replaced with a single lumen to provide inflation fluid to more than a single inflatable cuff on the endoscope assembly 20, so that the cuffs may be simultaneously inflated. Inflation of the cuffs 100a and 100b through the inflation lumens 702 and 704 thus allows an isolated body space 720 to be formed within the inter-cuff length 750 by sealably impressing the cuffs 100a and 100b against the body passage walls 732 of the body passage 730, as shown, for example, in the lower portion of Figure 7.

Lumens 706 and 708 may optionally be provided within the interior space 705 that communicate through openings 722 and 724 into the inter-cuff length 750. The lumens 706 and 708 may be fluidly connected to a variety of fluid or suction sources at the opposing ends 744 and 746 in order to accomplish a variety of diagnostic tasks. For example, the lumen 706 may be fluidly connected to a source of a solution (not shown) to introduce the solution into the isolated body space 720. The solution may then be subsequently withdrawn from the space 720 through another lumen 708 for analysis. Alternatively, the lumen 706 may be fluidly connected to a source of pressurized fluid (not shown) that may be used to distend the isolated body space 720 prior to the introduction of a solution into the space 720 by the lumen 708. Although a pair of lumens 706 and 708 is shown in Figure 7, it is understood that a single lumen, or more than two may optionally be used.

The endoscope assembly 20 advantageously allows the cuffs 100a and 100b to be separately and selectively inflated to permit the endoscope assembly 20 to sealably adjust to variations in thickness and elasticity of the body passage wall 732. The endoscope assembly 20 further advantageously allows a portion of the body passage 730 to be fluidly isolated from the remaining portion of the passage so that lavage, or any of the diagnostic procedures previously described, may be conducted in the isolated body space 720.

Figure 8 is a cross-sectional view of an endoscope assembly 30 in accordance with still another alternative embodiment of the invention. The assembly 30 includes an inflatable first cuff 800a and a spaced apart inflatable second cuff 800b, which are positioned on an outer surface of a disposable sheath 130. The cuff 800a has a non-uniform wall thickness, and includes a forward portion 801a, and a rear portion 802a that has a wall thickness that is less than the wall thickness of the forward portion 801a. The cuff 800b similarly has a non-uniform wall thickness, and also includes a forward portion 801b, and a rear portion 802b that has a wall thickness that is less than the wall thickness of the forward portion 801b. The sheath 130 encloses an interior space 705, and may be positioned on an insertion tube (not shown) that is comprised of a resilient material so that the tube may be flexed as it is positioned within an internal body passage 730. Alternatively, the insertion tube may be rigid.

Inflation lumens 702 and 704 may be positioned within the interior space 705, and may be fluidly connected to a source of an inflation fluid (not shown) at lumen ends 740 and 742. The lumens 702 and 704 communicate through the sheath 130 at openings 134a and 134b to allow the inflation fluid to separately and selectively inflate the first cuff 800a and the second cuff 800b. Alternatively, a single lumen 707 (shown in Figure 8 as a dotted line) may be used to provide inflation fluid to the first cuff 800a and the second cuff 800b so that the cuffs may be simultaneously inflated.

In operation, inflation of the first cuff 800a and the second cuff 800b through the inflation lumens 702 and 704 allows the cuffs 800a and 800b to be impressed against body passage wall 732 of a body passage 730. Further, the non-uniform wall thicknesses of the first cuff 800a and the second cuff 800b permit greater expansion of the rear portions 802a and 802b of the cuffs 800a and 800b than is obtained in the respective front portions 801a and 801b of the cuffs 800a and 800b when the cuffs 800a and 800b are inflated. The respective rear portions 802a and 802b of cuffs 800a and 800b thus develop a longitudinally-directed

biasing force that acts in a direction 810 when the inflated rear portions 802a and 802b contact the body passage wall 732. In alternate embodiments, the thicknesses of the front and rear portions 801 and 802 can be reversed so that the biasing force acts in an opposite direction.

Referring now to Figure 9, a cross-sectional view of the endoscope assembly 30 is shown with the first cuff 800a at least partially inflated, with the rear portion 802a of the cuff 800a contacting a portion of the body passage wall 732. In response to the biasing force developed by the rear portion 802a, the assembly 30 is urged along the passage 730 in the direction 810 from a first position 910 to a second position 920.

Figure 10 is a cross sectional view of the assembly 30 with the first cuff 800a in a deflated condition, and the second cuff 800b at least partially inflated. The rear portion 802b of the cuff 800b contacts a portion of the body passage wall 732 and develops a biasing force that further urges the assembly 30 along the passage 730 in the direction 810 from the second position 920 to a third position 1010. The second cuff 800b may then be deflated, and the process repeated. By alternately inflating and deflating the cuffs 800a and 800b in the manner described, the assembly 30 is able to incrementally move along the length of the body passage 730. Alternatively, for certain body passages 730 and for certain endoscopic procedures, it may be desirable to keep one of the cuffs 800a or 800b inflated at all times (*e.g.* to provide an anchor), and to successively inflate and deflate the other of the cuffs to provide the desired longitudinal movement. It may also be desirable to keep one of the cuffs 800a or 800b deflated (or to eliminate one of the cuffs 800a or 800b) and to employ a single cuff to provide the desired longitudinal movement in the manner described.

Although the foregoing discussion has described the sequential alternating inflation and deflation of the first cuff 800a and the second cuff 800b, in another embodiment, the cuffs 800a and 800b may be simultaneously inflated and deflated using the single lumen 707 to move the assembly 30 along the body passage 730. Further, although the endoscope

assembly 30 as depicted in Figures 8 through 10 has a pair of cuffs 800a and 800b, it is understood that the assembly 30 may be comprised of a plurality of inflatable cuffs located along the length of the assembly 30, and that the inflatable cuffs may be positioned along the length of the assembly 30 at varying distances. In addition, a portion of the plurality of cuffs may be oriented on the assembly 30 to apply a biasing force that urges the assembly 30 in a first direction to extend the assembly 30 into the body passage 730, while another portion of the plurality of cuffs are oriented on the assembly 30 to apply a biasing force in an opposing second direction to assist in the removal of the assembly 30 from the passage 730, as will be discussed in greater detail below, in connection with another embodiment.

It should also be understood that, although the foregoing embodiment discloses cuffs 800a and 800b having a variable wall thickness, other means may be used to obtain the differential expansion of the cuffs 800a and 800b in the manner described. For example, the composition of the material comprising the cuffs 800a and 800b may be formulated to provide the rear portions 802a and 802b with greater elasticity, so that greater expansion occurs in these portions, as opposed to the front portions 801a and 801b. Still further, internal structures, such as elastic cords 803 (Figure 9) or elastic webs 805 (Figure 10), for example, or other suitable structures, may be incorporated into the cuffs 800a and 800b that restrain the expansion of the front portions 801a and 801b, while permitting the corresponding rear portions 802a and 802b to freely expand.

The foregoing embodiment advantageously allows an endoscope assembly to develop a longitudinally-directed biasing force that permits the endoscope assembly to be positioned relatively deeply into a body passage, and further permits small, incremental movements of the endoscope assembly when properly positioned within the body passage. The foregoing embodiment further allows the endoscope assembly to be conveniently dislodged in situations where the assembly may become lodged in the passage.

As further shown in Figure 9, in yet another embodiment, the assembly 30 may include one or more sleeve members 807 that partially inhibit the expansion of one or more of the cuffs 800a, 800b. In the embodiment shown in Figure 9, the sleeve member 807 is attached to the outer surface of the sheath 130 and partially covers the first cuff 800a. As the first cuff 800a is inflated, the sleeve member 807 allows the rear portion 802a of the first cuff 800a to expand, and at least partially inhibits the expansion of the forward portion 802b. The sleeve member 807 may inhibit the expansion of the forward portion 802b by any means, including by being relatively less elastic than the first cuff 800a, or may simply add additional thickness to the forward portion 802b. Thus, the differential expansion of the cuffs 800a, 800b may be achieved, and the longitudinally-directed biasing force may be created, in an inexpensive manner by adding one or more sleeve members 807 to the assembly to achieve the beneficial results described above.

Figure 12 is a partial side view of an endoscope assembly 1100 according to still yet another embodiment of the invention. The assembly 1100 includes an inflatable first cuff 1110a and a spaced apart inflatable second cuff 1110b that are positioned on the outer surface of the sheath 130. The first cuff 1110a and the second cuff 1110b may be separately inflated, as described earlier in connection with other embodiments. As in the embodiment shown in Figures 8 through 10, the first cuff 1110a has a non-uniform wall thickness, which includes a forward portion 1111a, and a rear portion 1112a that has a wall thickness that is less than the wall thickness of the forward portion 1111a. The cuff 1110b also has a non-uniform wall thickness, including a forward portion 1112b and a rear portion 1111b. The forward portion 1112b has a wall thickness that is less than the wall thickness of the rear portion 1111b. The non-uniform wall thicknesses of the first cuff 1110a and the second cuff 1110b permit greater expansion of the portions 1112a and 1112b of the cuffs 1110a and 1110b than is obtained in the portions 1111a and 1111b of the cuffs 1110a and 1110b when the cuffs 1110a and 1110b are inflated. The portions 1112a and 1112b thus develop a

longitudinally-directed biasing force when the inflated portions 1112a and 1112b contact the body passage wall 732.

Turning now to Figure 13, a partial side view of the assembly 1100 is shown with the first cuff 1110a at least partially inflated. The rear portion 1112a of the cuff 1110a contacts the passage wall 732 and urges the assembly 1100 along the body passage 730 in a direction 1210. The cuff 1110a may be periodically inflated and deflated to move the assembly 1100 along the passage 730.

Referring now to Figure 14, a partial side view of the assembly 1100 is shown with the second cuff 1110b at least partially inflated. The front portion 1112b of the cuff 1110b contacts the passage wall 732 and urges the assembly 1100 along the body passage 730 in a direction 1220 that is opposite to the direction 1210 shown in Figure 13.

The foregoing embodiment advantageously permits the assembly 1100 to be moved along the passage 730 in a direction that positions the assembly 1100 further into the passage 730, and also permits the assembly 1100 to be moved in the opposite direction, which may be beneficial in preventing the assembly 1100 from being lodged in the passage 730, in addition to further assisting an operator to precisely position the assembly 1100 within the passage 730.

The above description of illustrated embodiments of the invention is not intended to be exhaustive or to limit the invention to the precise form disclosed. While specific embodiments of, and examples of, the invention are described in the foregoing for illustrative purposes, various equivalent modifications are possible within the scope of the invention, as those skilled in the relevant art will recognize. Moreover, the various embodiments described above can be combined to provide further embodiments. For example, the various embodiments of the inflatable endoscope cuffs as previously described may be advantageously positioned along the length of the endoscope at uniform or varying distances to provide a plurality of inflatable cuffs along the length of the sheath. Further,

different embodiments of the inflatable endoscope cuffs as previously described may be positioned at uniform or varying distances along the length of an endoscope to provide a plurality of different cuffs along the sheath to provide still further advantages. For example, the inflatable cuffs may be comprised of different materials or material thicknesses to obtain different inflation rates for the inflatable cuffs and/or different cuff volumes when the inflatable cuffs are inflated by the fluid passage. Accordingly, the invention is not limited by the disclosure, but instead the scope of the invention is to be determined entirely by the following claims.

CLAIMS

1. An endoscope assembly adapted to be inserted into an internal body passage, comprising:

an elongated insertion tube;

a sheath positioned over the insertion tube;

at least two radially expandable flexible members that sealably attach to the sheath to form at least two enclosed spaces capable of inflation, the flexible members being spaced apart along a length of the sheath and defining one or more isolated body spaces that extend between the members when the members are inflated within the body passage; and

at least one first fluid passage that fluidly communicates with the spaces.

2. The endoscope assembly according to claim 1 wherein the radially expandable flexible members comprise circumferential members, and wherein the enclosed spaces comprise annular enclosed spaces.

3. The endoscope assembly according to claim 1 wherein the radially expandable flexible members comprise circumferential members that, when inflated, are symmetrically disposed about the insertion tube.

4. The endoscope assembly according to claim 1 wherein the radially expandable flexible members comprise circumferential members that, when inflated, are asymmetrically disposed about the insertion tube.

5. The endoscope assembly according to claim 1 wherein the first fluid passage is adapted to be coupled to a source of pressurized fluid.

6. The endoscope assembly according to claim 1 wherein the at least two flexible members comprise a resilient material.

7. The endoscope assembly according to claim 1 wherein the at least one first fluid passage comprises a lumen coupled to at least one opening in the sheath, the lumen being coupleable to a source of pressurized fluid.

8. The endoscope assembly according to claim 1, further comprising at least one second fluid passage that fluidly communicates with the one or more isolated body spaces.

9. The endoscope assembly according to claim 5 wherein the at least one second fluid passage comprises a lumen extending from an opening in the sheath, the lumen being coupleable to a source of a fluid solution.

10. The endoscope assembly according to claim 5 wherein the at least one second fluid passage comprises a lumen extending from an opening in the flexible sheath to a suction source.

11. The endoscope assembly according to claim 1 wherein the at least one first fluid passage comprises a first lumen extending from a first opening in the sheath that communicates with a first annular space, and a second lumen that extends from a second opening that communicates with a second annular space.

12. The endoscope assembly according to claim 1 wherein at least one of the flexible members includes a reentrant fold in the sheath to form a flap with a base adjoining the insertion tube and an edge disposed away from the base.

13. The endoscope assembly according to claim 1 wherein at least one of the flexible members includes a first reentrant fold in the sheath to form a first edge and a second reentrant fold in the sheath to form a second edge, the first and second edges substantially abutting the opening.

14. The endoscope assembly according to claim 1 wherein the opening in the sheath comprises a plurality of openings and wherein the flexible member comprises a first reentrant fold in the sheath to form a first circumferential edge and a second reentrant fold in the sheath to form a second circumferential edge, the first and second edges sealably attached to the sheath proximate to the openings, the flexible member being further sealably attached to the sheath at a position intermediate between the first and second circumferential edges.

15. The endoscope assembly according to claim 1 wherein the flexible members comprise an annular ring of a flexible material positioned over the opening and having an inner face and an outer face, the inner face being substantially in facial contact with the sheath when not inflated, and the outer face being disposed away from the sheath and having first and second peripheral edges which are sealably attached to the sheath.

16. The endoscope assembly according to claim 1 wherein the flexible member comprises a toroidally-shaped member with an inner circumference and an outer

circumference, the inner circumference being in facial contact with the sheath, and the outer circumference being disposed away from the sheath, the inner circumference having an opening positioned over the opening in the sheath and being sealably attached to the sheath at the inner circumference.

17. The endoscope assembly according to claim 1 wherein the opening in the sheath comprises a plurality of openings and wherein the flexible member comprises an annular ring of a flexible material with an inner face and an outer face, the inner face being substantially in facial contact with the sheath when not inflated, and the outer face being disposed away from the sheath and having first and second peripheral edges which are sealably attached to the sheath, the inner face being further sealably attached to the sheath at a position intermediate between the first and second peripheral edges.

18. The endoscope assembly according to claim 1 wherein the flexible members comprise an elastomeric material.

19. The endoscope assembly according to claim 1 wherein the flexible members comprise an elastomer with a durometer value of between approximately 30 and 50.

20. The endoscope assembly according to claim 1 wherein the flexible members comprise a material with a thickness of approximately about 0.003 inches to approximately about 0.010 inches.

21. The endoscope assembly according to claim 1 wherein the flexible members are sealably attached to the flexible sheath with an adhesive.

22. The endoscope assembly according to claim 1 wherein the flexible members are sealably attached to the flexible sheath by thermal fusion.

23. The endoscope assembly according to claim 1 wherein the flexible members are sealably attached to the flexible sheath with a retaining cord .

24. The endoscope assembly according to claim 1 wherein at least one of the flexible members includes a non-uniform wall thickness.

25. The endoscope assembly according to claim 1 wherein at least one of the flexible members includes a first portion having a first wall thickness and a second portion having a second wall thickness, the first thickness being different from the second thickness.

26. The endoscope assembly according to claim 1 wherein at least one of the flexible members includes a first portion having a first elasticity and a second portion having a second elasticity, the first elasticity being different than the second elasticity.

27. The endoscope assembly according to claim 1 wherein at least one of the flexible members includes an internal structure disposed within the associated body space and attached to a first portion of the flexible member that partially inhibits expansion of the first portion.

28. The endoscope assembly according to claim 1, further comprising a sleeve member attached to an outer surface of the sheath and engaged with a first portion of at least one of the flexible members, the sleeve member partially inhibiting an expansion of the first portion.

29. A sheath having a body portion adapted to at least partially encapsulate an insertion tube of an endoscope, comprising:

at least two radially expandable flexible members sealably attached to the body portion to form at least two enclosed spaces capable of inflation, each space having at least one first opening that projects through the body portion, and wherein the flexible members are spaced apart along a length of the body portion to define one or more isolated body spaces that extend between the members when the members are inflated within the body passage.

30. The sheath according to claim 29 wherein at least one of the radially expandable flexible members comprises a circumferential member, and wherein at least one of the enclosed spaces comprises an annular enclosed space.

31. The sheath according to claim 29 wherein at least one of the radially expandable flexible members comprises a circumferential member that, when inflated, is symmetrically disposed about the insertion tube.

32. The sheath according to claim 29 wherein at least one of the radially expandable flexible members comprises a circumferential member that, when inflated, is asymmetrically disposed about the insertion tube.

33. The sheath according to claim 29 wherein at least one of the flexible members includes an internal structure disposed within the corresponding enclosed space and attached to a first portion of the at least one flexible member that partially inhibits expansion of the first portion.

34. The sheath according to claim 29, further comprising a sleeve member attached to an outer surface of the body portion and engaged with a first portion of at least one of the flexible members, the sleeve member partially inhibiting an expansion of the first portion.

35. The sheath according to claim 29 wherein the at least one first opening is adapted to be coupled to a source of pressurized fluid.

36. The sheath according to claim 29 wherein the at least two flexible members comprise a resilient material.

37. The sheath according to claim 29 wherein the at least one first opening further comprises a lumen coupled to the at least one first opening, the lumen being coupleable to a source of pressurized fluid.

38. The sheath according to claim 29, further comprising at least one second opening in the body portion that fluidly communicates with the one or more isolated body spaces.

39. The sheath according to claim 38 wherein the at least one second opening comprises a lumen extending from the second opening, the lumen being coupleable to a source of a fluid solution.

40. The sheath according to claim 38 wherein the at least one second opening comprises a lumen extending from the second opening, the lumen being coupleable to a suction source.

41. A method of forming an endoscope assembly, comprising:

providing a sheath;

providing a first fluid passage that extends through the sheath to define a first opening in the sheath;

forming a first flexible member about the sheath and defining a first space in fluid communication with the first opening, the first space being adapted to be inflated;

providing a second fluid passage that extends through the sheath to define a second opening in the sheath; and

forming a second flexible member about the sheath and defining a second space in fluid communication with the second opening, the second space being adapted to be inflated, the second inflatable member being spaced apart from the first inflatable member along the tube to define an isolated body space therebetween.

42. The method according to claim 41 wherein forming a first flexible member comprises forming a first circumferential member, and wherein the first space comprises a first annular space.

43. The method according to claim 41 wherein forming a first flexible member comprises forming a first circumferential member that, when inflated, is symmetrically disposed about the sheath.

44. The method according to claim 41 wherein forming a first flexible member comprises forming a first circumferential member that, when inflated, is asymmetrically disposed about the sheath.

45. The method according to claim 41 wherein forming a first flexible member comprises forming a first flexible member that includes an internal structure disposed within the corresponding enclosed space and attached to a first portion of the first flexible member that partially inhibits expansion of the first portion.

46. The method according to claim 41 wherein providing a sheath comprises providing a sheath including a sleeve member attached to an outer surface thereof, the sleeve member being engaged with a first portion of at least one of the first and second flexible members, the sleeve member partially inhibiting an expansion of the first portion.

47. The method according to claim 41 wherein providing a first fluid passage comprises forming a lumen extending from the first opening in the sheath to a source of pressurized fluid.

48. The method according to claim 41 wherein providing a second fluid passage comprises forming a lumen extending from the second opening in the flexible sheath to a source of pressurized fluid.

49. The method according to claim 41, further comprising providing a third fluid passage that extends through the sheath to define a third opening that fluidly communicates with the isolated body space.

50. The method according to claim 49 wherein providing a third fluid passage further comprises forming a lumen extending from the third opening in the sheath to a source of pressurized fluid.

51. The method according to claim 49 wherein providing a third fluid passage comprises forming a lumen extending from the third opening in the sheath to a suction source.

52. The method according to claim 41, further comprising :

providing a fourth fluid passage that extends through the sheath to define a fourth opening in the sheath; and

forming a third flexible member in fluid communication with the fourth opening in the sheath to define an enclosed third space adapted to be inflated, the third inflatable member being spaced apart from the second inflatable member along the tube to define a second isolated body space that extends between the second and the third members.

53. The method according to claim 52, further comprising:

providing a fifth fluid passage that extends through the sheath to define a fifth opening that fluidly communicates with the second isolated body space.

54. The method according to claim 52 wherein providing a fifth fluid passage comprises forming a lumen extending from the fifth opening in the sheath to a source of pressurized fluid.

55. The method according to claim 52 wherein providing a fifth fluid passage comprises forming a lumen extending from the fifth opening in the sheath to a suction source.

56. The method according to claim 41 wherein forming a first flexible member includes forming a first flexible member having a non-uniform wall thickness.

57. The method according to claim 56 wherein forming a second flexible member includes forming a second flexible member having a non-uniform wall thickness.

58. The method according to claim 41 wherein forming a first flexible member includes forming a first flexible member having a first portion with a first wall thickness and a second portion with a second wall thickness, the first wall thickness being different from the second wall thickness.

59. The method according to claim 58 wherein forming a second flexible member includes forming a second flexible member having a first portion with a first wall thickness and a second portion with a second wall thickness, the first wall thickness being different from the second wall thickness.

60. The method according to claim 41 wherein forming a first flexible member includes forming a first flexible member having a first portion with a first elasticity and a second portion with a second elasticity, the first elasticity being different from the second elasticity.

61. The method according to claim 60 wherein forming a second flexible member includes forming a second flexible member having a first portion with a first elasticity and a second portion with a second elasticity, the first elasticity being different from the second elasticity.

62. A method of using an endoscope assembly within an internal passage, comprising:

positioning a sheath having at least two spaced apart and radially expandable members at least partially over an insertion tube of an endoscope;

at least partially inserting the insertion tube and sheath into the internal passage; and

inflating the radially expandable members to form at least one isolated body space therebetween.

63. The method according to claim 62, further comprising directing a fluid into the at least one isolated body space from a fluid source.

64. The method according to claim 63, further comprising directing a fluid into the at least one isolated body space from a pressurized fluid source to distend the space.

65. The method according to claim 62, further comprising applying suction to the at least one isolated body space from a suction source to remove a fluid from the space.

66. An endoscope assembly for insertion into an internal body passage, comprising:

an elongated insertion tube;

a sheath at least partially encapsulating the insertion tube;

at least one radially expandable flexible member sealably coupled to the sheath and adapted to be inflated against the internal body passage and to exert a force along a longitudinal axis of the insertion tube when inflated against the internal body passage; and

at least one fluid passage coupleable to a source of pressurized fluid that fluidly communicates with the at least one member.

67. The endoscope assembly according to claim 66 wherein the at least one radially expandable flexible member comprises a circumferential member.

68. The endoscope assembly according to claim 66 wherein the at least one radially expandable flexible member comprises a circumferential member that, when inflated, is symmetrically disposed about the insertion tube.

69. The endoscope assembly according to claim 66 wherein the at least one radially expandable flexible member comprises a circumferential member that, when inflated, is asymmetrically disposed about the insertion tube.

70. The endoscope assembly according to claim 66 wherein the at least one flexible member includes an internal structure disposed within a corresponding enclosed space and attached to a first portion of the at least one flexible member that partially inhibits expansion of the first portion.

71. The endoscope assembly according to claim 66 wherein the sheath includes a sleeve member attached to an outer surface of the sheath and engaged with a first portion of the flexible member, the sleeve member partially inhibiting an expansion of the first portion.

72. The endoscope assembly according to claim 66 wherein the at least one fluid passage comprises a lumen extending from an opening in the sheath to the source of pressurized fluid.

73. The endoscope assembly according to claim 66 wherein the at least one radially expandable flexible member includes a first portion capable of a first expansion when inflated, and a second portion capable of a second expansion when inflated, the first expansion being greater than the second.

74. The endoscope assembly according to claim 73 wherein the first portion comprises a first material, and the second portion comprises a second material.

75. The endoscope assembly according to claim 73 wherein the first portion has a first elasticity, and the second portion has a second elasticity, the first elasticity being greater than the second elasticity.

76. The endoscope assembly according to claim 73 wherein the first portion has a first elasticity, and the second portion has a second elasticity, the first elasticity being greater than the second elasticity.

77. The endoscope assembly according to claim 73 wherein the first portion has a first cross sectional thickness, and the second portion has a second cross sectional thickness, the first cross sectional thickness being different from the second cross sectional thickness.

78. A sheath having a body portion adapted to at least partially encapsulate an insertion tube of an endoscope, the insertion tube being insertable into an internal body passage, comprising:

at least one radially expandable flexible member sealably coupled to the body portion and adapted to be inflated against the internal body passage and to exert a force along a longitudinal axis of the insertion tube when inflated against the internal body passage, and wherein the body portion includes at least one opening that projects through the body portion and is coupleable to a source of pressurized fluid that fluidly communicates with the at least one member.

79. The sheath according to claim 78 wherein the at least one radially expandable flexible member comprises a circumferential member.

80. The sheath according to claim 78 wherein the at least one radially expandable flexible member comprises a circumferential member that, when inflated, is symmetrically disposed about the insertion tube.

81. The sheath according to claim 78 wherein the at least one radially expandable flexible member comprises a circumferential member that, when inflated, is asymmetrically disposed about the insertion tube.

82. The sheath according to claim 78 wherein the at least one opening comprises a lumen extending from the opening in the body portion to the source of pressurized fluid.

83. The sheath according to claim 78 wherein the at least one radially expandable flexible member includes a first portion capable of a first expansion when inflated, and a second portion capable of a second expansion when inflated, the first expansion being greater than the second.

84. The sheath according to claim 83 wherein the first portion comprises a first material, and the second portion comprises a second material.

85. The sheath according to claim 84 wherein the first material has a first elasticity, and the second material has a second elasticity, the first elasticity being greater than the second elasticity.

86. The sheath according to claim 78 wherein the first portion has a first elasticity, and the second portion has a second elasticity, the first elasticity being greater than the second elasticity.

87. The sheath according to claim 78 wherein the first portion has a first thickness, and the second portion has a second thickness, the first thickness being different from the second thickness.

88. A method of using an endoscope assembly within an internal passage, comprising:

positioning a sheath having at least one radially expandable member over an insertion tube of an endoscope, the at least one radially expandable member being adapted to be inflated against the internal body passage and to exert a force along a longitudinal axis of the insertion tube when inflated against the internal body passage;

at least partially inserting the insertion tube with the sheath positioned thereon into the passage; and

inflating the at least one member to move the insertion tube along the passage.

89. The method according to claim 88, further comprising deflating the at least one member.

90. The method according to claim 88 wherein inflating the at least one member to move the insertion tube includes moving the insertion tube into the passage.

91. The method according to claim 88 wherein inflating the at least one member to move the insertion tube includes moving the insertion tube out of the passage.

92. The method according to claim 88 wherein positioning a sheath having at least one radially expandable member over an insertion tube of an endoscope, comprises positioning a sheath having first and second radially expandable members, and wherein inflating the at least one member includes inflating the first and second radially expandable members.

93. The method according to claim 92 wherein inflating the first and second members includes simultaneously inflating the first and second members to move the members in a first direction.

94. The method according to claim 92 wherein inflating the first and second members includes sequentially inflating the first and second members to move the members in a first direction.

95. The method according to claim 92 wherein inflating the first and second members includes inflating the first member to move in a first direction, and inflating the second member to move in a second direction.

96. The method according to claim 88 wherein inflating the at least one radially expandable member comprises inflating a circumferential member that, when inflated, is symmetrically disposed about the insertion tube.

97. The method according to claim 88 wherein inflating the at least one radially expandable member comprises inflating a circumferential member that, when inflated, is asymmetrically disposed about the insertion tube.

98. The method according to claim 88 wherein positioning a sheath having at least one radially expandable member over an insertion tube of an endoscope comprises positioning a sheath having a radially expandable member that includes a first portion capable of a first expansion when inflated, and a second portion capable of a second expansion when inflated, the first expansion being greater than the second expansion.

99. An assembly, comprising:

a sheath having a body portion adapted to at least partially encapsulate an insertion tube;

at least one radially expandable flexible member sealably coupled to the body portion and defining an inner region adapted to be inflated; and

at least one fluid passage coupled to the flexible member and fluidly communicating with the inner region.

100. The assembly according to claim 99 wherein the at least one fluid passage extends through the body portion of the sheath.

101. The assembly according to claim 99 wherein the at least one fluid passage is coupleable to a source of pressurized fluid that fluidly communicates with the inner region.

102. The assembly according to claim 99 wherein the at least one radially expandable flexible member comprises a circumferential member.

103. The assembly according to claim 99 wherein the at least one radially expandable flexible member includes a first portion capable of a first expansion when inflated, and a second portion capable of a second expansion when inflated, the first expansion being greater than the second.

104. The assembly according to claim 103 wherein the first portion comprises a first material, and the second portion comprises a second material.

105. The assembly according to claim 103 wherein the first portion has a first elasticity, and the second portion has a second elasticity, the first elasticity being greater than the second elasticity.

106. The assembly according to claim 103 wherein the first portion has a first thickness, and the second portion has a second thickness, the first thickness being different from the second thickness.

107. The assembly according to claim 99, further comprising an insertion tube, the body portion of the sheath at least partially encapsulating the insertion tube.

108. A method of forming an endoscope assembly, comprising:

providing a sheath having a body portion adapted to at least partially encapsulate an insertion tube;

forming at least one radially expandable flexible member sealably coupled to the body portion and defining an inner region adapted to be inflated; and

providing at least one fluid passage coupled to the flexible member and fluidly communicating with the inner region.

109. The method according to claim 108 wherein providing at least one fluid passage comprises providing at least one fluid passage extending through the body portion of the sheath.

110. The method according to claim 108 wherein forming at least one radially expandable flexible member comprises forming a first circumferential member, and wherein the inner region comprises an annular region.

111. The method according to claim 108 wherein forming at least one radially expandable flexible member comprises forming a flexible member having an internal structure disposed within the inner region and attached to a first portion of the flexible member, the internal structure at least partially inhibiting expansion of the first portion.

112. The method according to claim 108 wherein providing a sheath comprises providing a sheath including a sleeve member attached to an outer surface thereof,

the sleeve member being engaged with a first portion of the at least one flexible member, the sleeve member at least partially inhibiting an expansion of the first portion.

113. The method according to claim 108 wherein forming at least one flexible member includes forming a flexible member having a non-uniform wall thickness.

114. The method according to claim 108 wherein forming at least one flexible member includes forming a flexible member having a first portion with a first elasticity and a second portion with a second elasticity, the first elasticity being different from the second elasticity.

115. A method of performing a medical procedure, comprising:

positioning a sheath having at least one radially expandable member over an instrument, the at least one radially expandable member being adapted to be inflated;

inserting the at least one radially expandable member at least partially into a bodily passage; and

inflating the at least one radially expandable member into engagement with the bodily passage.

116. The method according to claim 115 wherein inflating the at least one radially expandable member comprises inflating the at least one radially expandable member to move the instrument along the passage.

117. The method according to claim 115 wherein inflating the at least one radially expandable member comprises inflating the at least one radially expandable member to prevent movement of the instrument within the passage.

118. The method according to claim 115 wherein inflating the at least one radially expandable member comprises inflating the at least one radially expandable member to at least partially obstruct the passage.

119. The method according to claim 115 wherein inflating the at least one radially expandable member comprises inflating the at least one radially expandable member to displace tissue proximate the passage.

120. The method according to claim 115 wherein positioning a sheath having at least one radially expandable member over an instrument comprises positioning a sheath having first and second radially expandable members.

121. The method according to claim 120 wherein inflating the at least one radially expandable member comprises simultaneously inflating the first and second expandable members.

122. The method according to claim 120 wherein inflating the at least one radially expandable member comprises sequentially inflating the first and second expandable members.

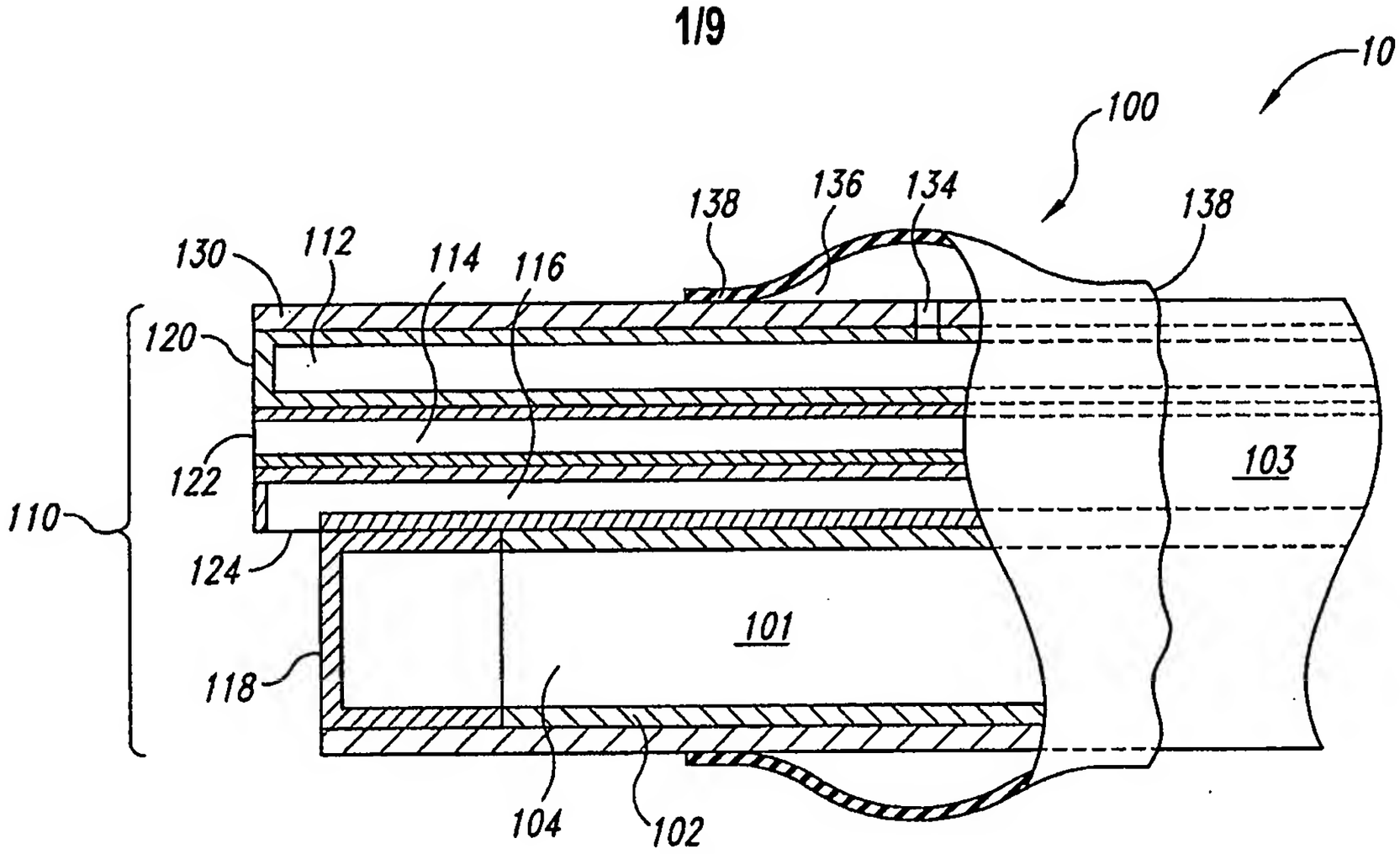
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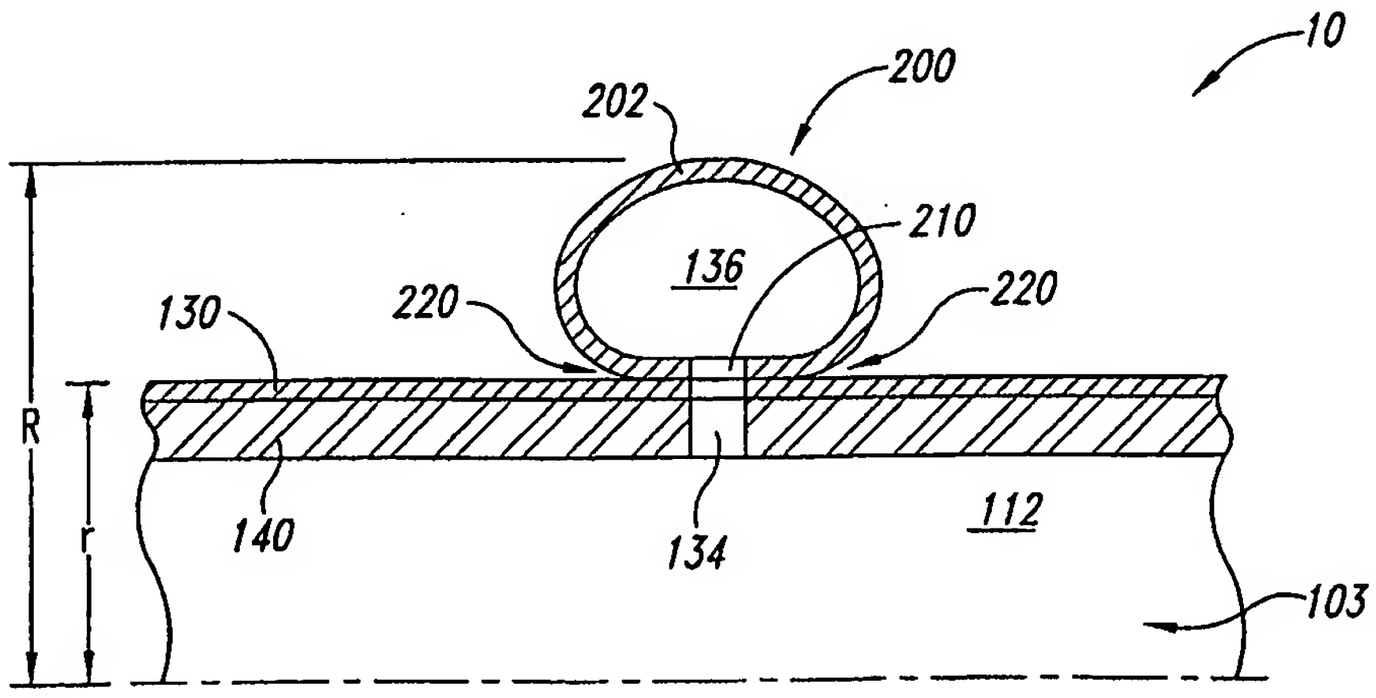
FIG.1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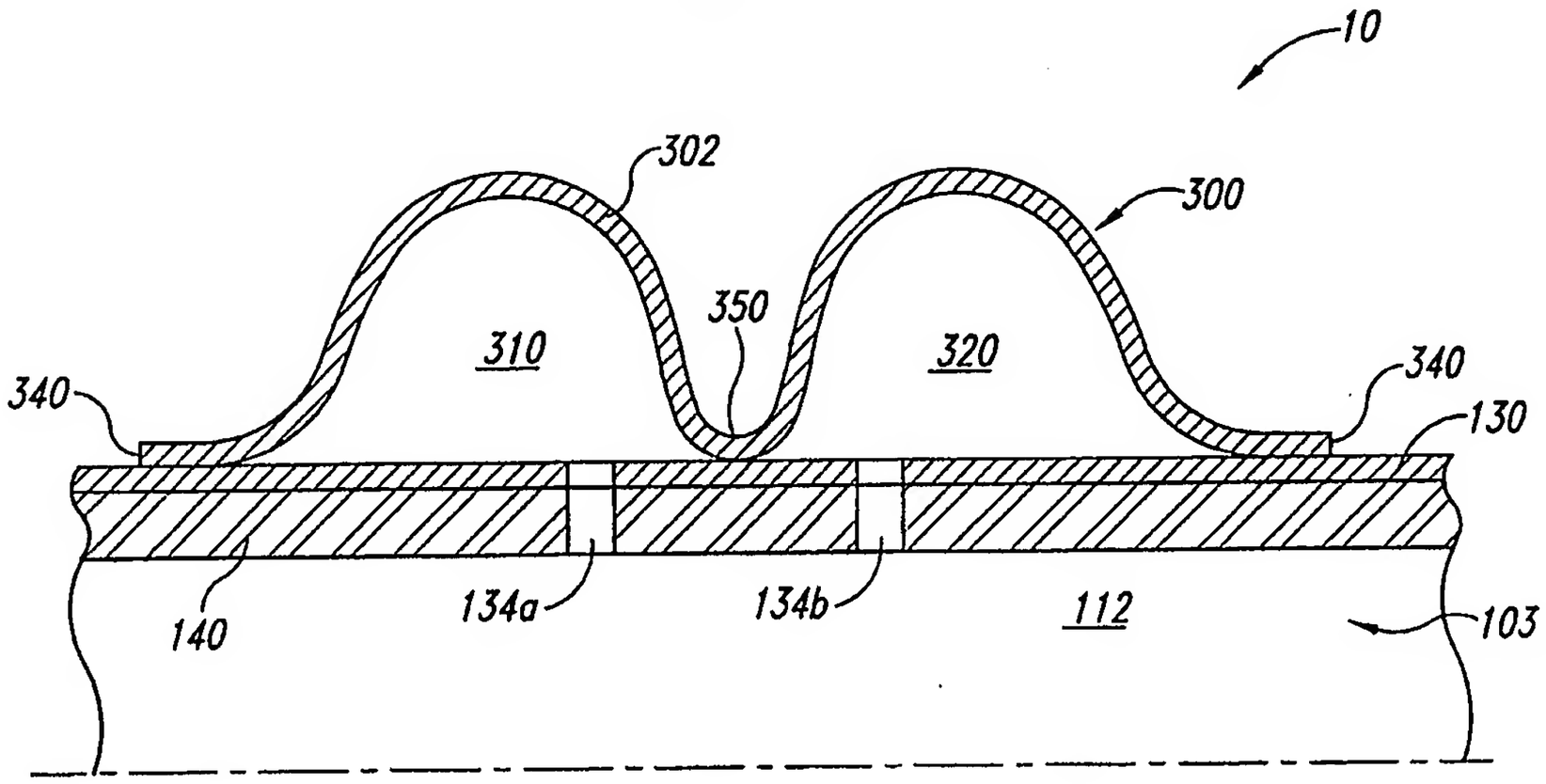
103

FIG.2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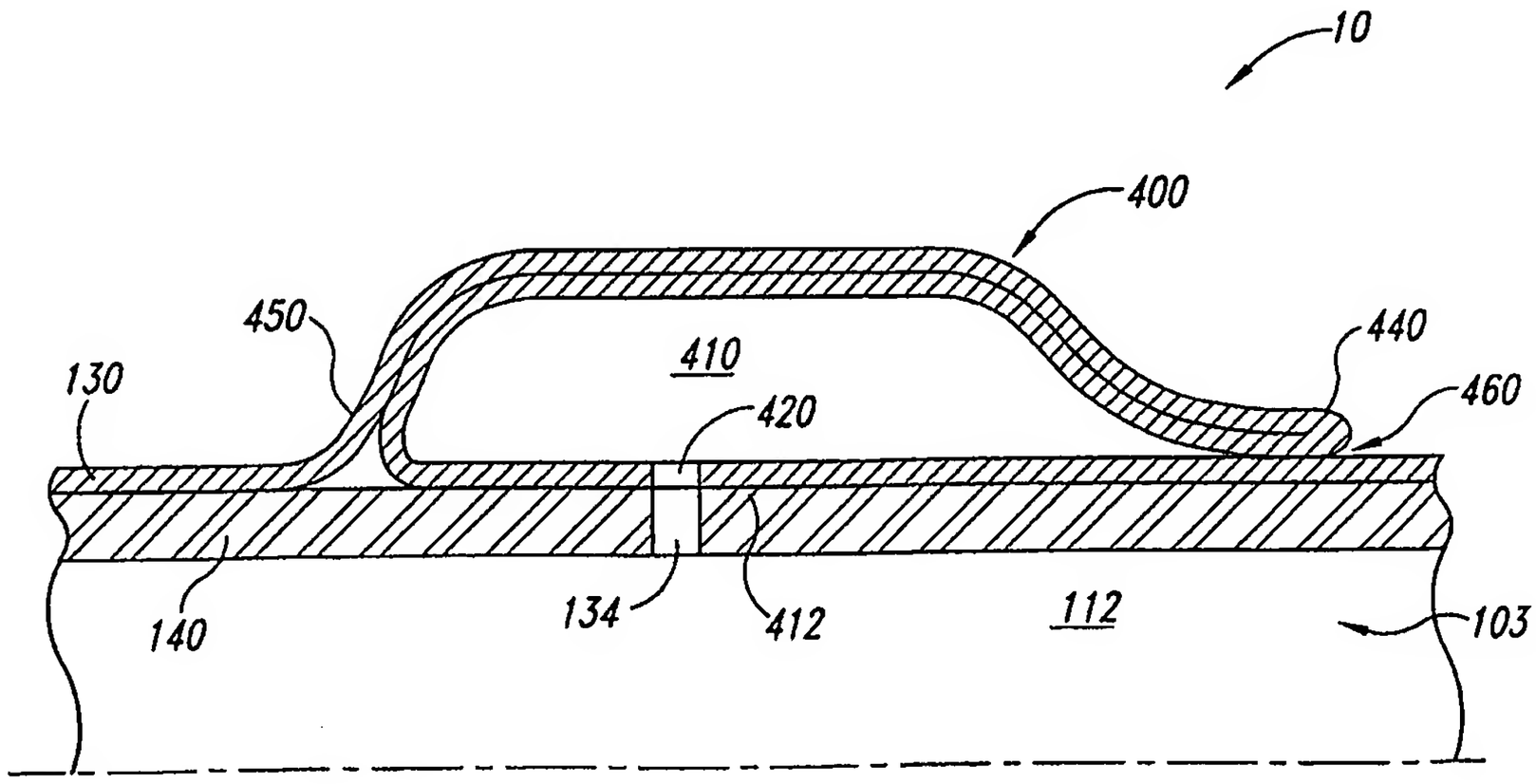
350
310
320
340
340
130
140
134a
134b
112
103

FIG.3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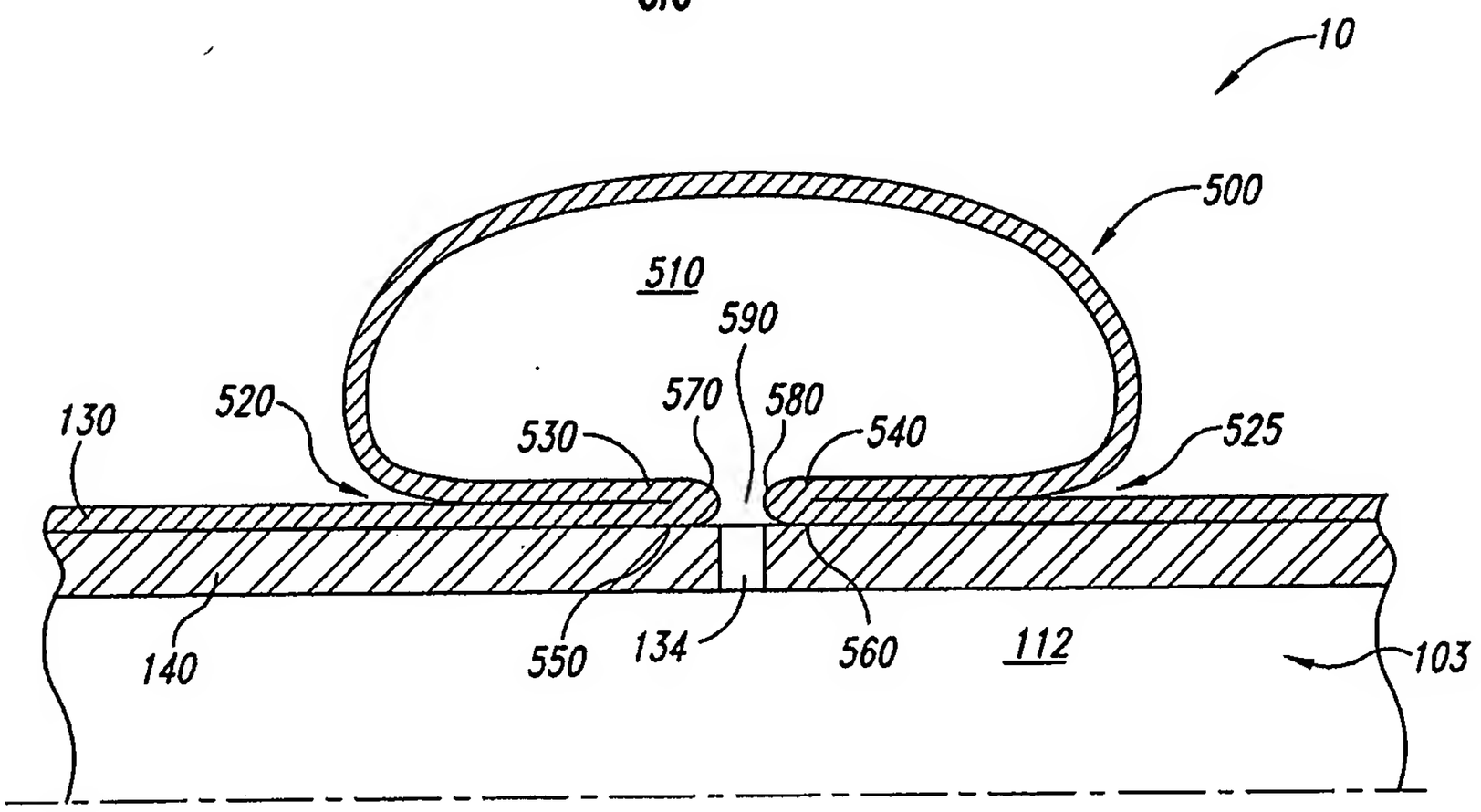
103

FIG.4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510
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530
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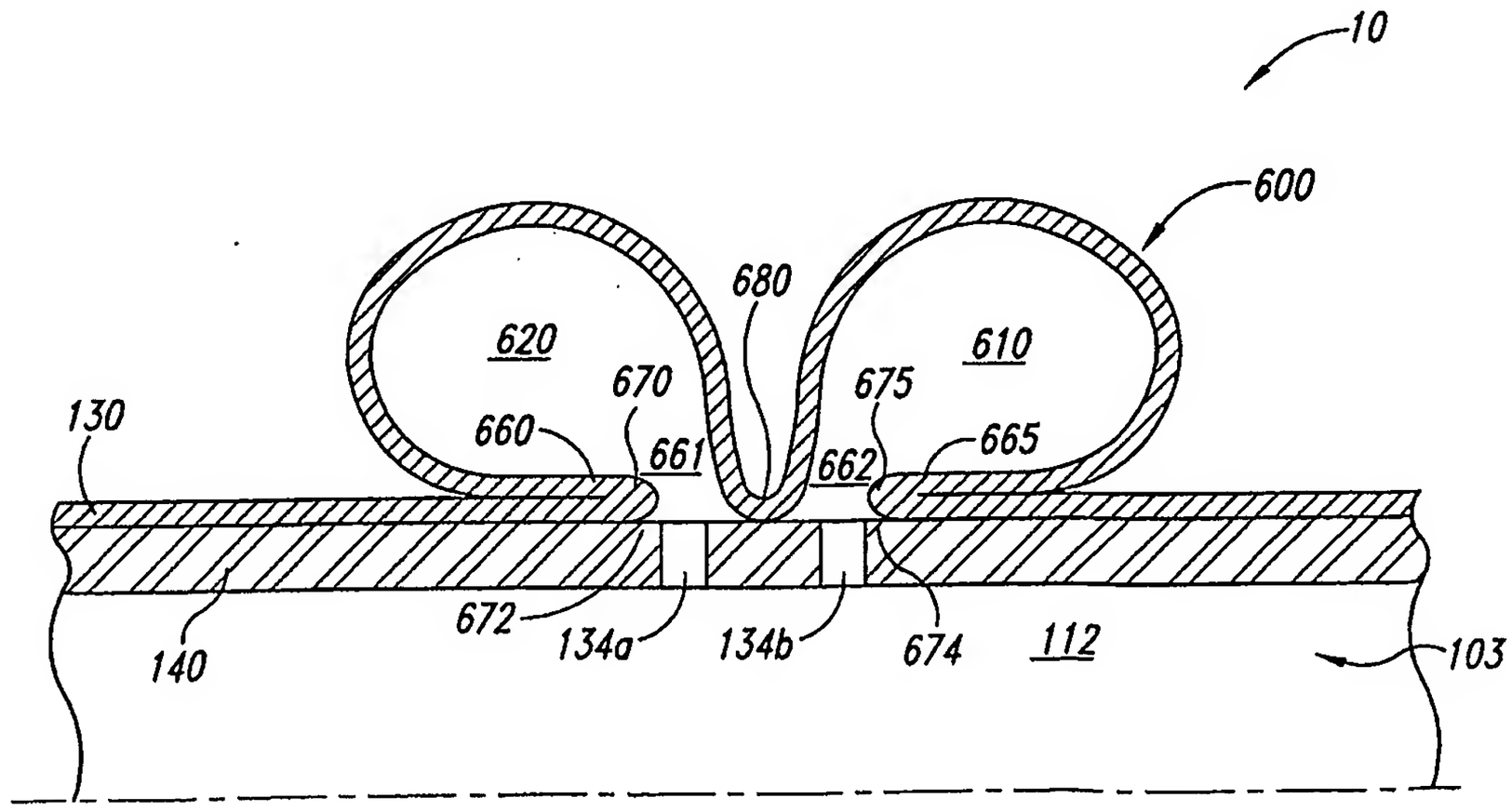
525
140
550
134
560
112
103

FIG.5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134a
134b
674
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112
103

FIG.6

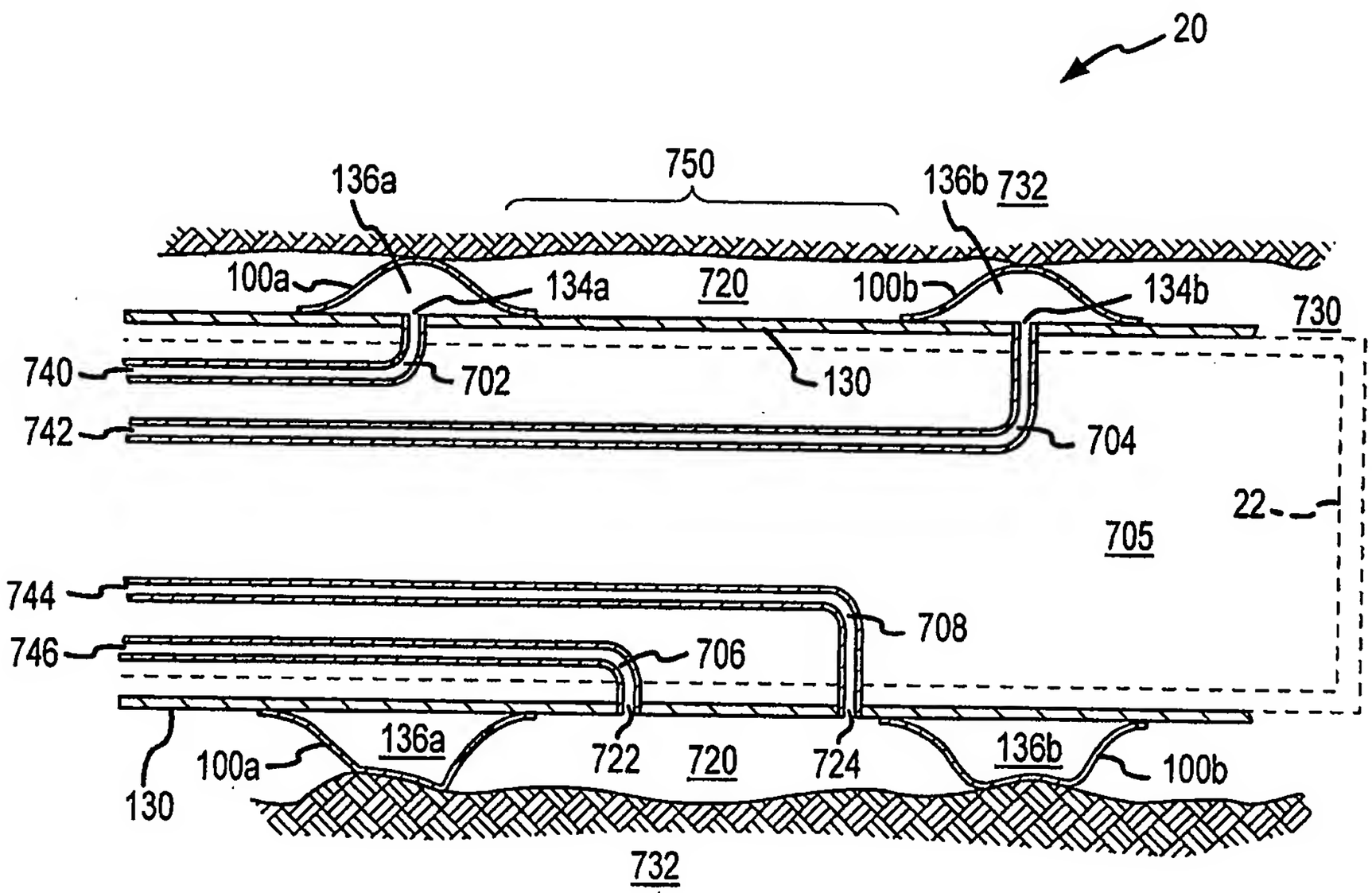

20
136a
750
136b
732
100a
134a
720
100b
134b
730
740
702
130
742
704
22
705
744
708
746
706
136a
722
720
724
136b
100a
100b
130
732

FIG.7

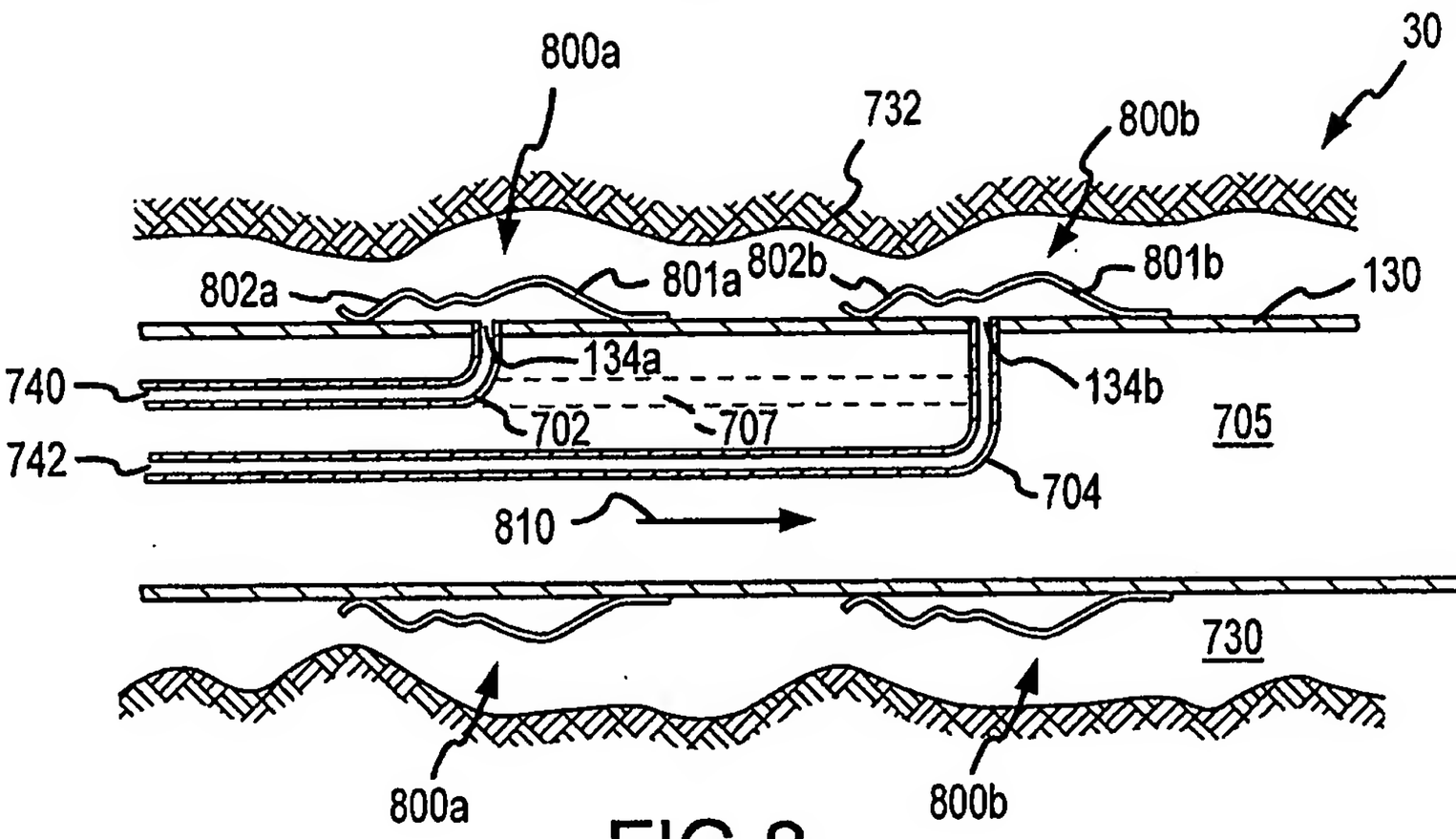
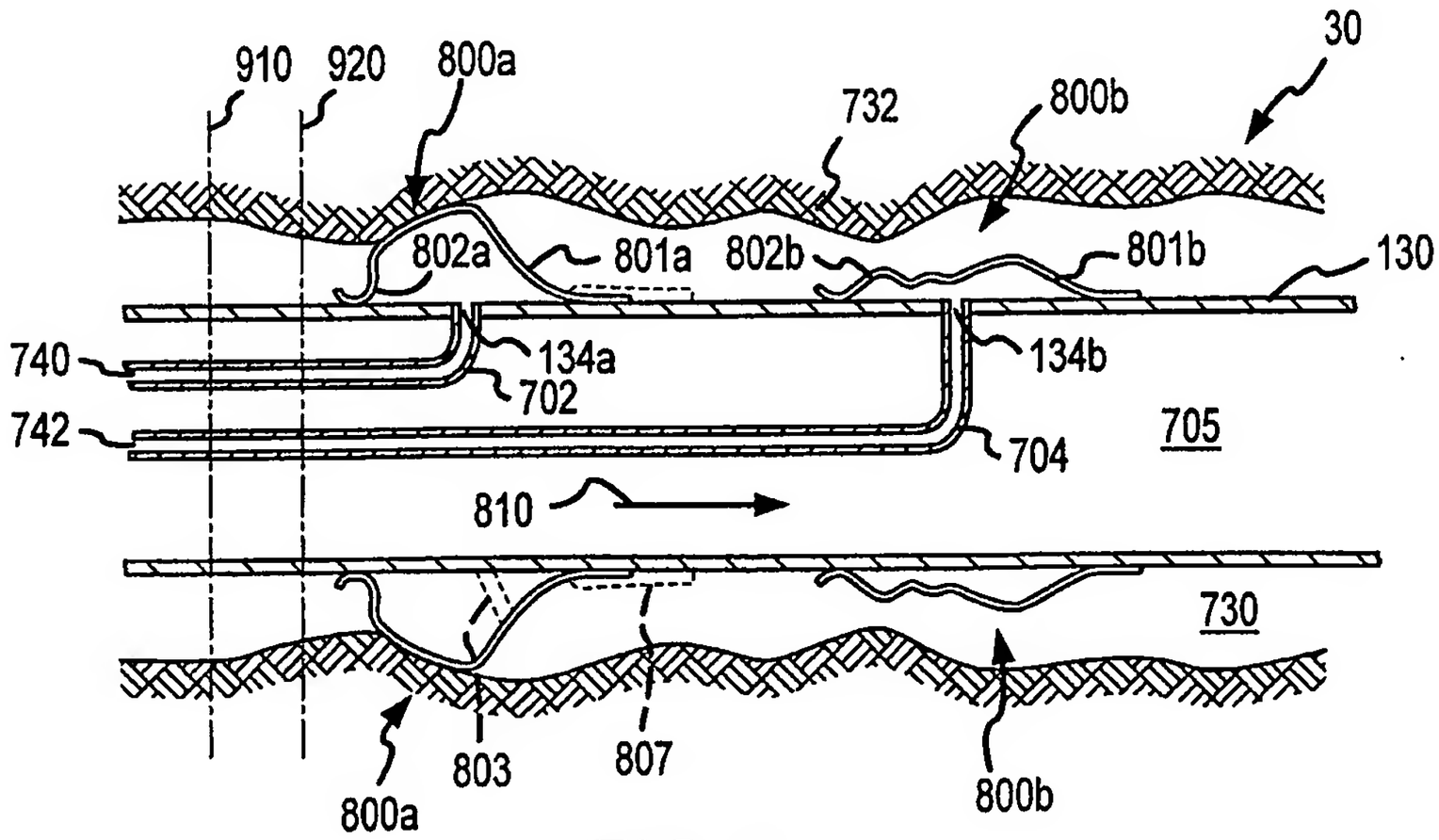

800a
732
800b
30
802a
801a
802b
801b
130
134a
134b
740
702
707
705
742
704
810
730
800a
800b

FIG.8


910
920
800a
732
800b
30
802a
801a
802b
801b
130
740
134a
134b
702
742
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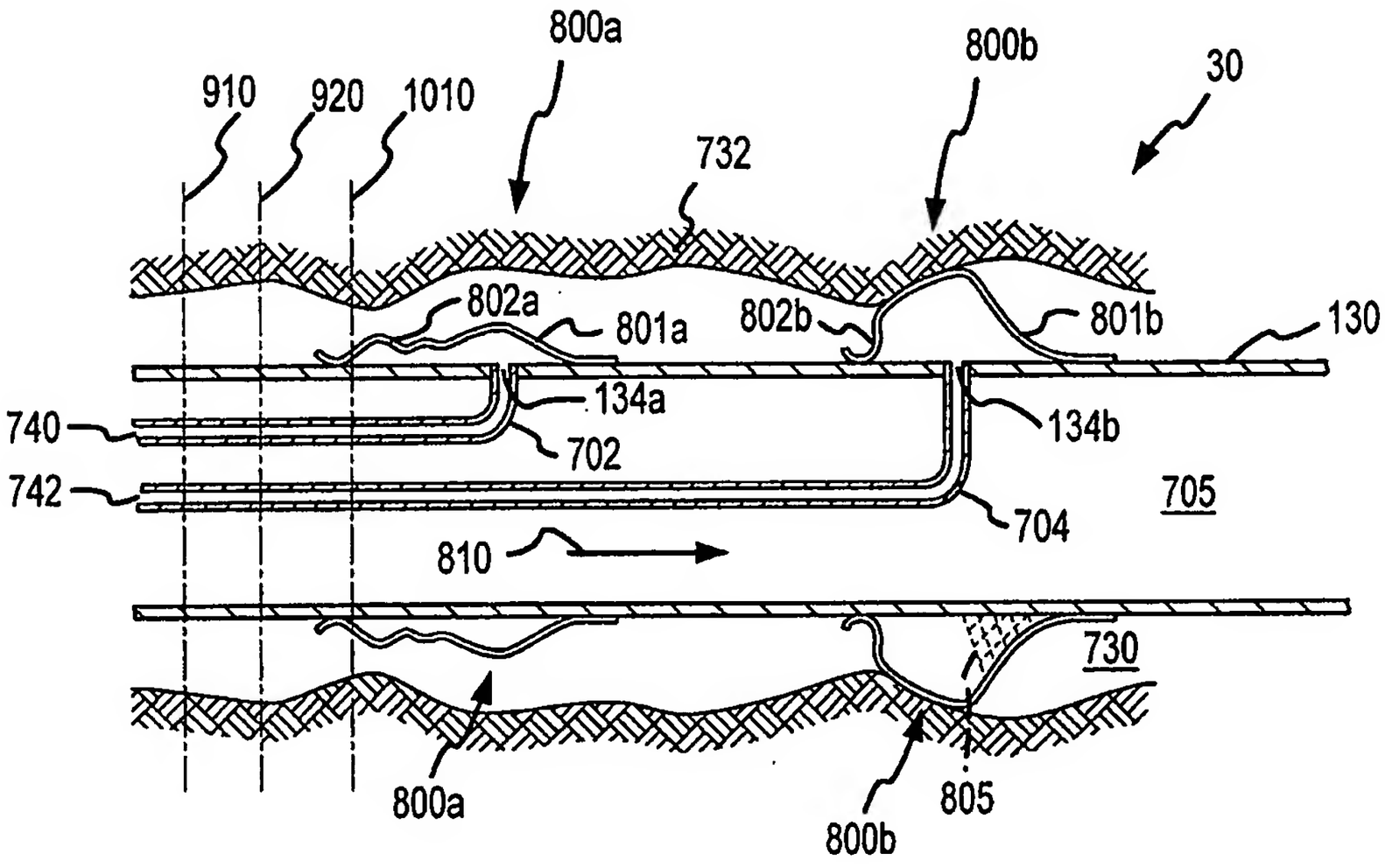
704
810
730
803
807
800a
800b

FIG.9


800a
800b
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910
920
1010
732
802a
801a
802b
801b
130
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134b
740
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704
705
810
730
800a
800b
805

FIG.10

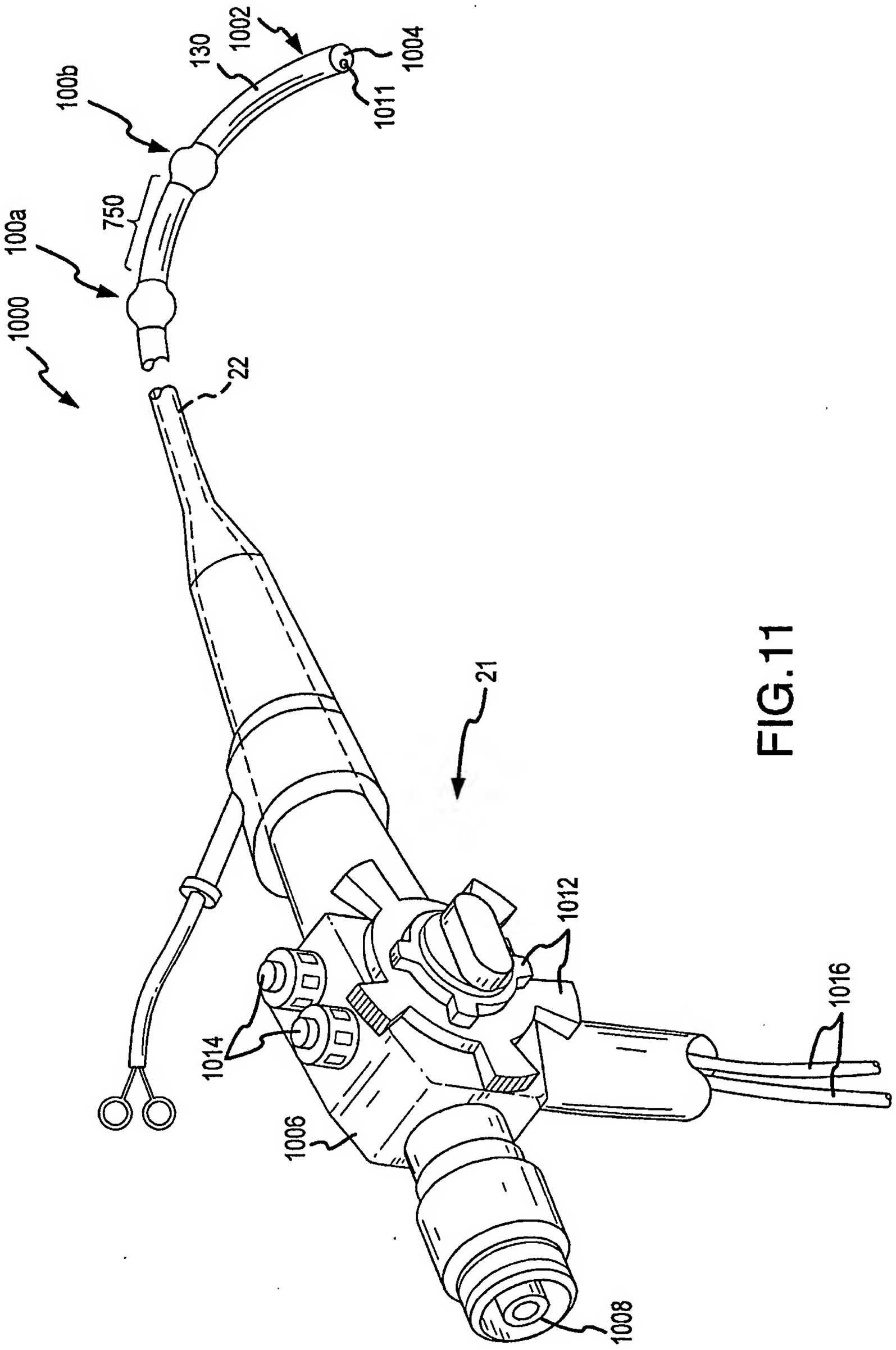
130
1002
1004
1011
100b
750
100a
1000
22
21
1012
1016
1014
1006
1008

FIG.11

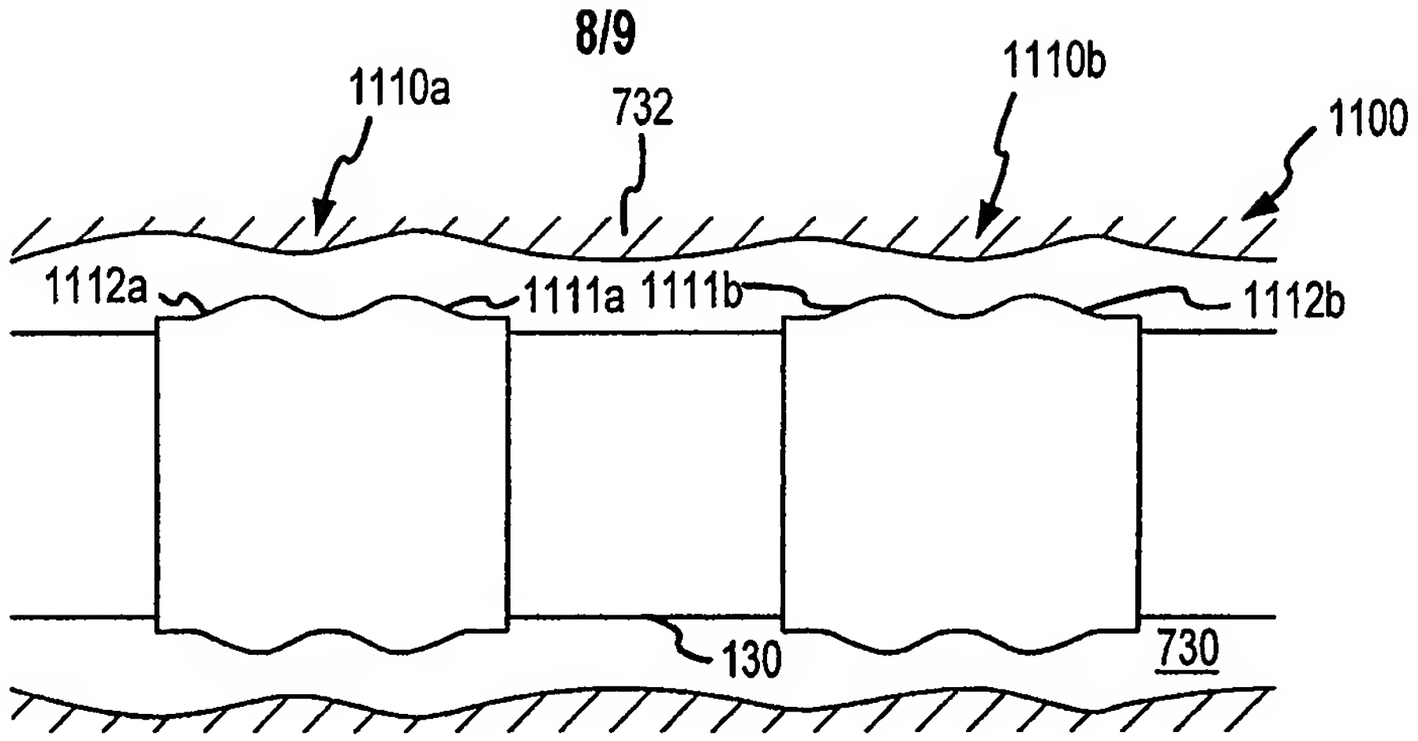

FIG.12

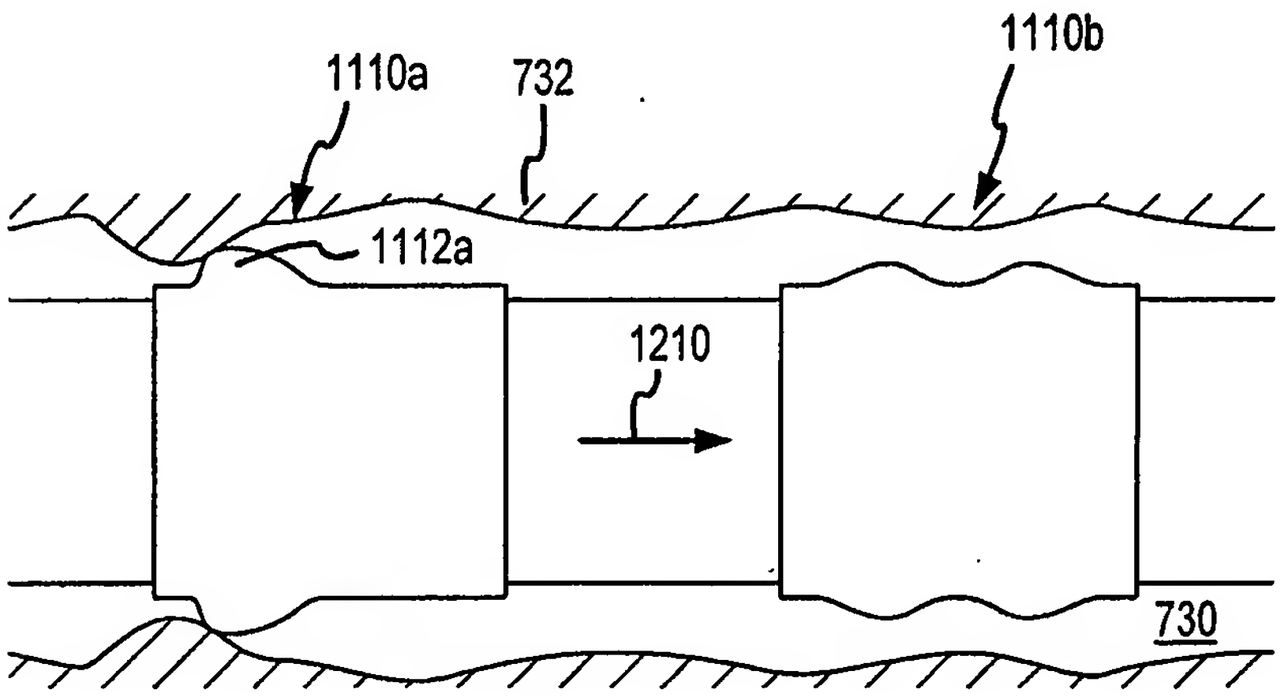

FIG.13

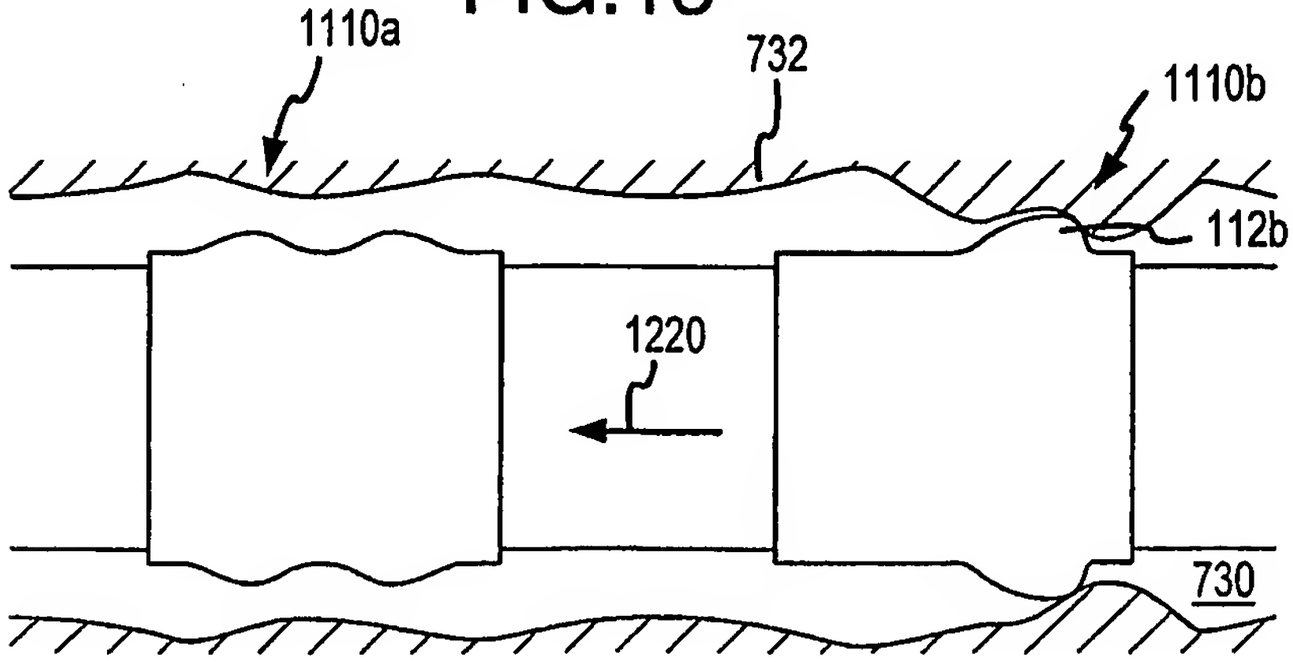

FIG.14

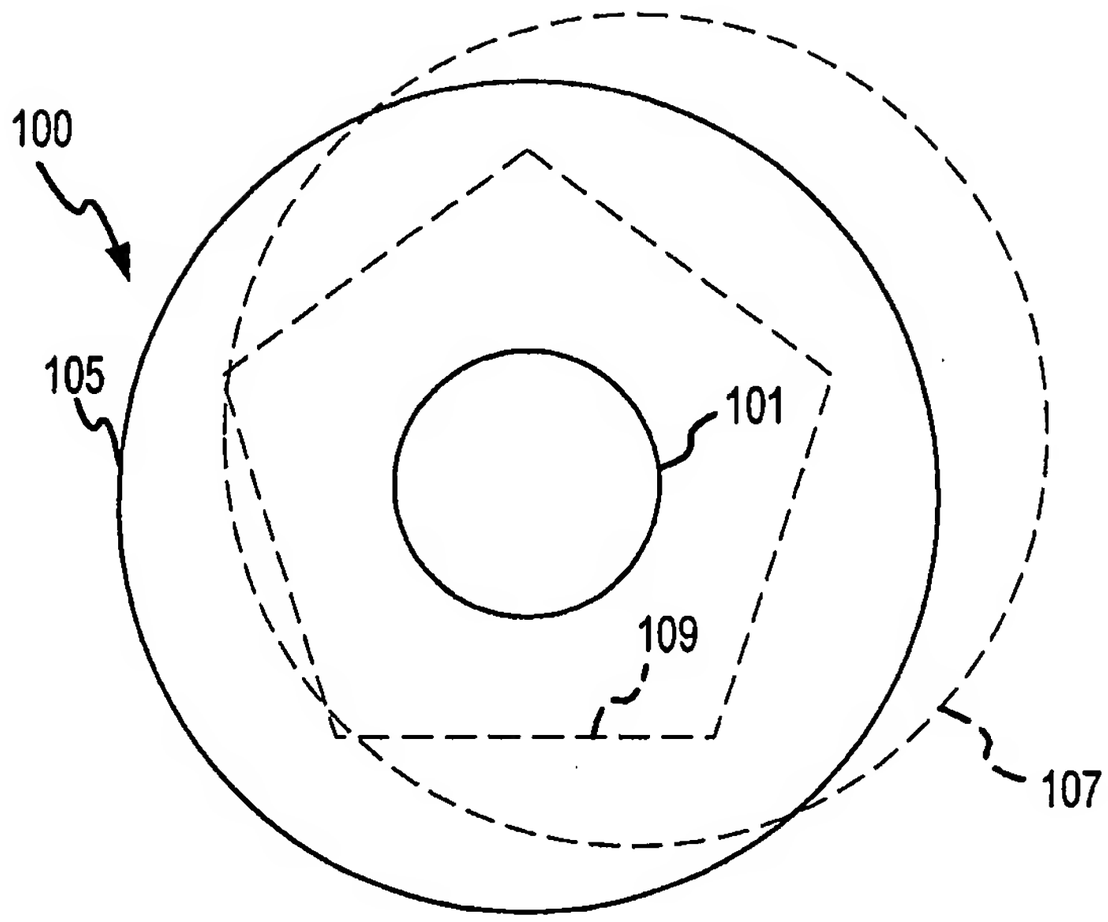

FIG.15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US03/07068

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61M 5/00
US CL : 600/116
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 600/116, 114, 121, 115, 152, 204, 166; 606/108, 153

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X, P	US 6,461,294 B1 Oneda et al) 08 October 2002, see entire document.	1-31, 33-43, 45-68, 82-96, 98-122
A	US 5,840,013 A (Lee et al) 11 November 1998.	1-69
A	US 5,628,753 A (Cracauer et al) 13 May 1997.	1-122
A	US 5,425,738 A (Gustafson et al) 20 June 1995.	1-122
A	US 4,148,307 A (Utsugi) 10 April 1979.	1-122

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 May 2003 (27.05.2003)	08 JUL 2003
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230	Authorized officer Leonid M Pastovsky Telephone No. 703-308-0861

Form PCT/ISA/210 (second sheet) (July 1998)